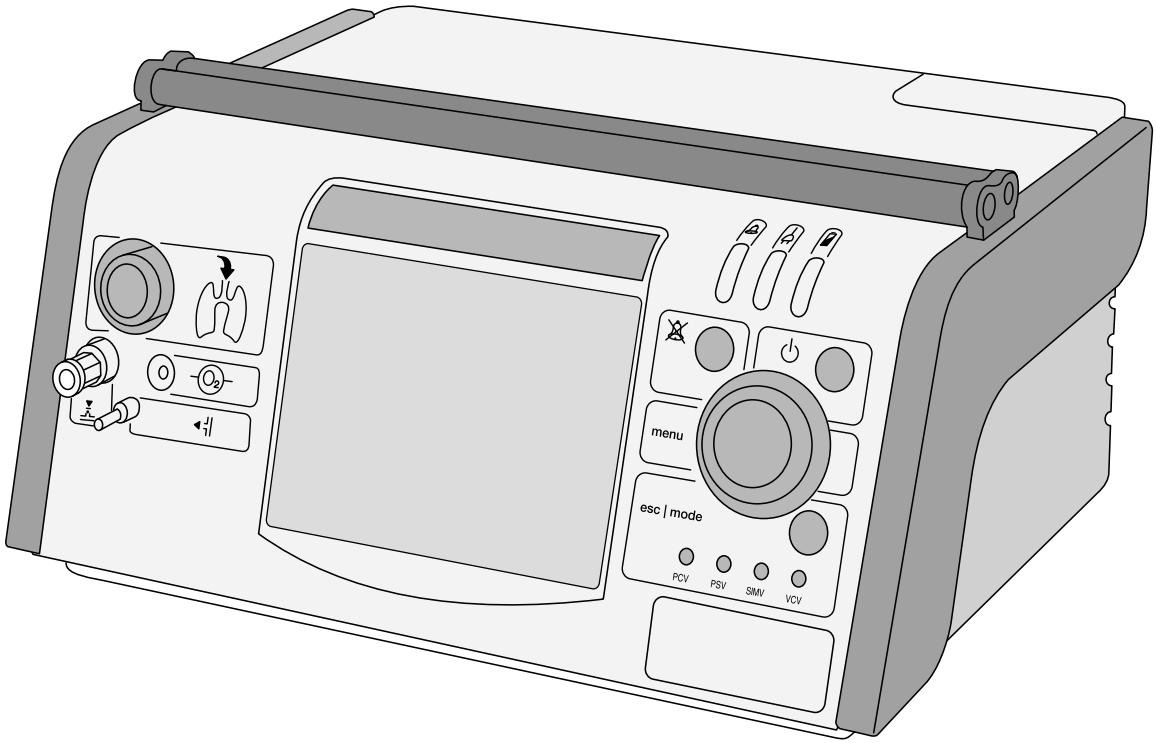
HOFFRICHTER
Quality makes the Difference

CARATT I



User's Manual

Ventilator

as of device software 2.104

SERIAL NUMBER

Every HOFFRICHTER GmbH device is supplied with a serial number for traceability purposes.

Please enter your device's serial number here. You will find the serial number on the rating plate on the back of the device.

Serial number: .....

Please always quote the serial number for all queries and complaints.

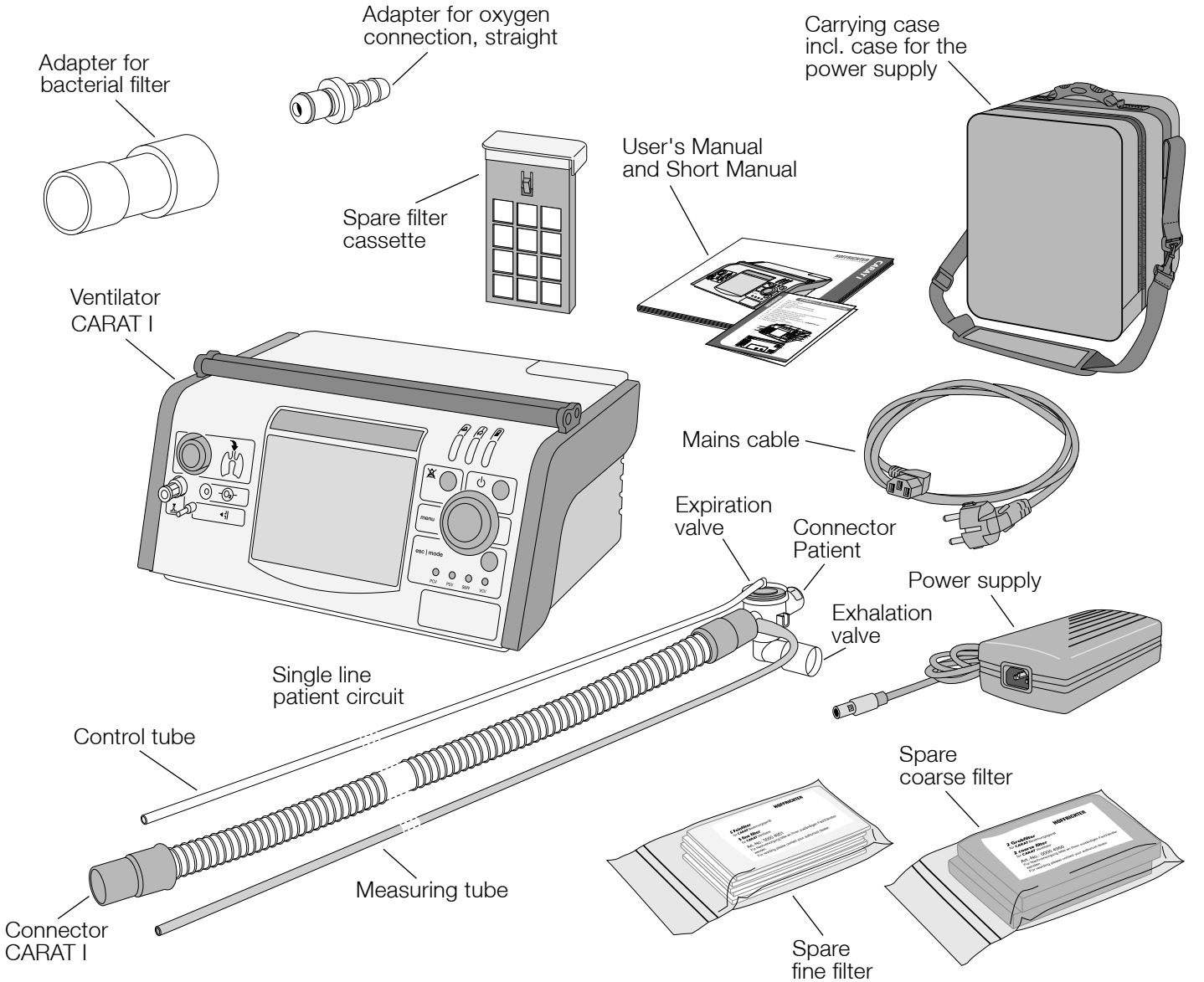
CONFORMITY

CE 0123

The CARAT I ventilator complies with the requirements of Directive 93/42/EEC.

CONTENTS

SCOPE OF DELIVERY



GENERAL

INFORMATIONEN ON USER'S MANUAL

Read this user's manual through carefully before using the ventilator for the first time.

Follow the safety and cleaning instructions in particular.

Keep the manual in a safe place close to the device so that you can refer to it immediately if necessary.

SYMBOLS ON THE RATING PLATE

Observe the warning and safety instructions in the user's manual

BF application part

Protection class II (protective insulation)

CE conformity declaration

Manufacturer

Do not dispose of the device in the household waste. Please contact the relevant customer services department to find out how to dispose of the device properly.

SYMBOLS USED IN THIS USER'S MANUAL

Important information is denoted by symbols in this user's manual. Be sure to follow these instructions in order to avoid accidents, personal injury and material damage.

In addition, the local accident prevention regulations and general safety regulations in force in the area of use must be observed.

This symbol denotes general safety instructions. Follow these instructions to avoid accidents, personal injury or material damage.

⚠WARNING

This symbol denotes hazardous situations that may lead to serious injuries or death.

⚠CAUTION

This symbol denotes hazardous situations that may lead to moderately severe injuries.

NOTICE

This symbol denotes situations that may lead to material damage or damage to the device.

IMPORTANT

This symbol denotes information, tips and instructions for the efficient, error-free use of the device.

SAFETY INFORMATION

GENERAL SAFETY INSTRUCTIONS

- Settings on the ventilator may only and exclusively be made by qualified and trained medical personnel under the supervision of a physician. The ventilator may only be operated by persons who have completely read and fully understood these User's Manual and have familiarized themselves with the system before putting it into operation. Any non-observance of these instructions may result in dangerous situations for the patient.
- The ventilator may only be used under the responsibility of and on prescription by the physician.
- The ventilator may only be used on patients whose clinical picture requires its application.
- Please take utmost care to ensure that the patient remains connected to the tubing system during ventilation.
- It is not permitted to operate the ventilator with flammable anesthetics or room air containing explosive gases. This may cause fire or explosion.
- Before being reused on a different patient, all parts coming into contact with the respiratory gas must be treated hygienically
- The directions given in these user's manual and the applicable regulations of the particular hospital or nursing home must be adhered to while hygienically treating and cleaning the ventilator.
- We recommend to use the ventilator with the tubing system tested and released by the manufacturer. Any use of other tubing systems may yield different results.

- When a nasal or full face mask is used for noninvasive ventilation, this mask must not contain any expiration opening.
- When using with a single line patient circuit, the controlled expiration valve must not meet any resistance during exhalation and must allow quick ventilation of the ventilation tube system.
- In order to ensure patient safety, the device must be operated in such a way that all adjustable alarms are activated and adjusted to the patient.
- Never ignore any audible alarm signals. Such signals indicate conditions which require immediate action.
- The ventilator must be subjected to the technical safety check every six months and to inspection and maintenance measures once a year.
- In case of extraordinary efforts on the patient's part, there may be the risk of hyperventilation in all ventilation modes with inspiration triggering.
- Do not steam-sterilize the system in the autoclave.
- Replace filters and other parts which are connected to the patient at regular intervals. Dispose of the parts replaced according to the regulations for used medical material and/or according to local environment protection rules.

- The connection of accessories or other components at the ventilator may increase the pressure at the patient connection during the expiration cycle.
- Please ensure that the total resistance of the patient circuit and the accessories used does not exceed 6 hPa with a flow of 60 l/min (on adults) and 30 l/min (on children).
- Any modification to the device poses a threat to its serviceability and is not permitted.
- Only use masks that have been prescribed for your treatment by a physician.
- Only use the mask after instruction by a qualified medical person and clarify in particular the intake of medicines and possible contraindications and side effects associated with the use of the mask.
- Please note the operating, transport and storage conditions.
- If temperatures fall below - 5 °C or rise above + 50 °C, proper functioning of the ventilator may be impaired.

INSTALLATION REQUIREMENTS AND TRANSPORT

- To ensure reliable operation, place the Ventilator on a safe and plane base. The air inlet on the rear of the system as well as all venting slots must not be covered or blocked.
- The display of the ventilator as well as the alarm LEDs must not be covered and must be permanently visible.
- Do not place any objects onto the ventilator.
- The housing of the ventilator does not provide any-protection against ingress of water.
- The system must never be stored or transported at an ambient temperature below - 10 °C or above + 50 °C.
- The system must not be exposed to direct solar radiation.
- Due to electromagnetic interference, the ventilator must not be set up in the immediate vicinity of other devices. If this is unavoidable, the ventilator must be monitored with respect to error-free and proper operation.
- Do not put the device near water containers (baths).

INSTRUCTIONS BEFORE COMMISSIONING

- Whenever the device is put into operation, a functional check must be performed beforehand (see page 74).
- Any ventilator that is not functioning properly may pose a risk to the patient or operator. If the system fails to start properly or if the self-tests performed automatically on system start fail to be completed successfully, it is not permitted to continue operation of the system. Please notify the service agency in such a case.
- Place the device in such a way that the mains plug is easily accessible so that it can be unplugged quickly in the event of a hazard.
- Do not use the device if the housing or the cable of the device or the power supply are damaged.

ELECTRICAL SAFETY

- Only the supplied power supply unit (PCM120 PS24 bzw. SNP-A129-M) may be used for operating the ventilator.
- Do not use any electrically conducting or electro statically chargeable patient tubes.
- The device must never be put near other devices or equipment such as defibrillators, diathermy units, mobile phones, microwaves, remote controlled toys, etc. Electromagnetic fields that exceed 10 V/m may adversely affect the operation of the ventilator.
- Please pull off the power plug to disconnect CARAT I from external power supply.
- Disconnect the power plug before cleaning the ventilator.
- The use of accessories or power supplies which are not approved by us for the device may lead to increased emission of electromagnetic radiation or reduced resistence to interference.
- During certain examinations or treatments, mutual interference between the ventilator and other medical devices may occur. Observe the information regarding electromagnetic compatibility and monitor the devices with regard to error-free and proper operation.
- Do not reach for the device under any circumstances should it fall into water.
- Do not try to open the device. Maintenance and repairs may only be performed by personnel authorized by HOFFRICHTER GmbH.

INDENDED USE

⚠WARNING
The use of the device contrary to its intended use can lead to a hazard to the health of the patient.

CARAT I is intended for ventilation of patients which are not completely dependent on mechanical ventilation. The device is suitable for ventilation of adults as well as of children with a tidal volume of 50 ml and higher. CARAT I has been designed specifically for use in home care but is also applicable for use in hospitals.

Ventilation is either pressure controlled or volume controlled and is ensured by setting one of the ventilation modes listed below:

- PCV – Pressure Controlled Ventilation
  Pressure controlled or pressure controlled assisted ventilation
- PSV – Pressure Supported Ventilation
- SIMV – Synchronous Intermittent Mandatory Ventilation
- VCV – Volume Controlled Ventilation
  Volume controlled or volume controlled assisted ventilation

Both invasive ventilation (e.g. via tracheostoma) and non-invasive ventilation (via a ventilation mask) are possible. CARAT I provides the technical features required for operation with a single line patient circuit. The system can be connected to a low-pressure gas source for ventilation with an increased oxygen concentration. In addition, it is also possible to combine CARAT I with a humidifier.

⚠CAUTION
The CARAT I ventilator must not be used as a life-support device.

CONTRAINDICATIONS

The following conditions may be a contraindication for non-invasive ventilation:

- Severe cardiac arrhythmia
- Severe hypotension
- Severe epistaxis
- Pneumothorax or pneumomediastinum
- Pneumoencephalus
- Cranial trauma
- Status after cranial or brain surgery
- Acute inflammation of the paranasal sinuses, middle ear infection or a perforated ear drum
- Aspiration hazard

In individual cases, the attending physician must decide on the therapy.

SIDE EFFECTS

The following undesired side effects may occur in connection with artificial respiration:

Invasive ventilation:

- Complications due to tube / tracheal cannula

Mask ventilation:

- Pressure points and skin defects in the face
- Eye irritation due to leaks
- Gastric inflation
- Aspiration
- Sinusitis
- Nose bleeds

General complications of mechanical ventilation:

- Pulmonary barotrauma / volutrauma caused by ventilation
- Ventilator-associated pneumonia
- Effects on the cardio-vascular system

DESCRIPTION OF THE DEVICE

FRONT VIEW

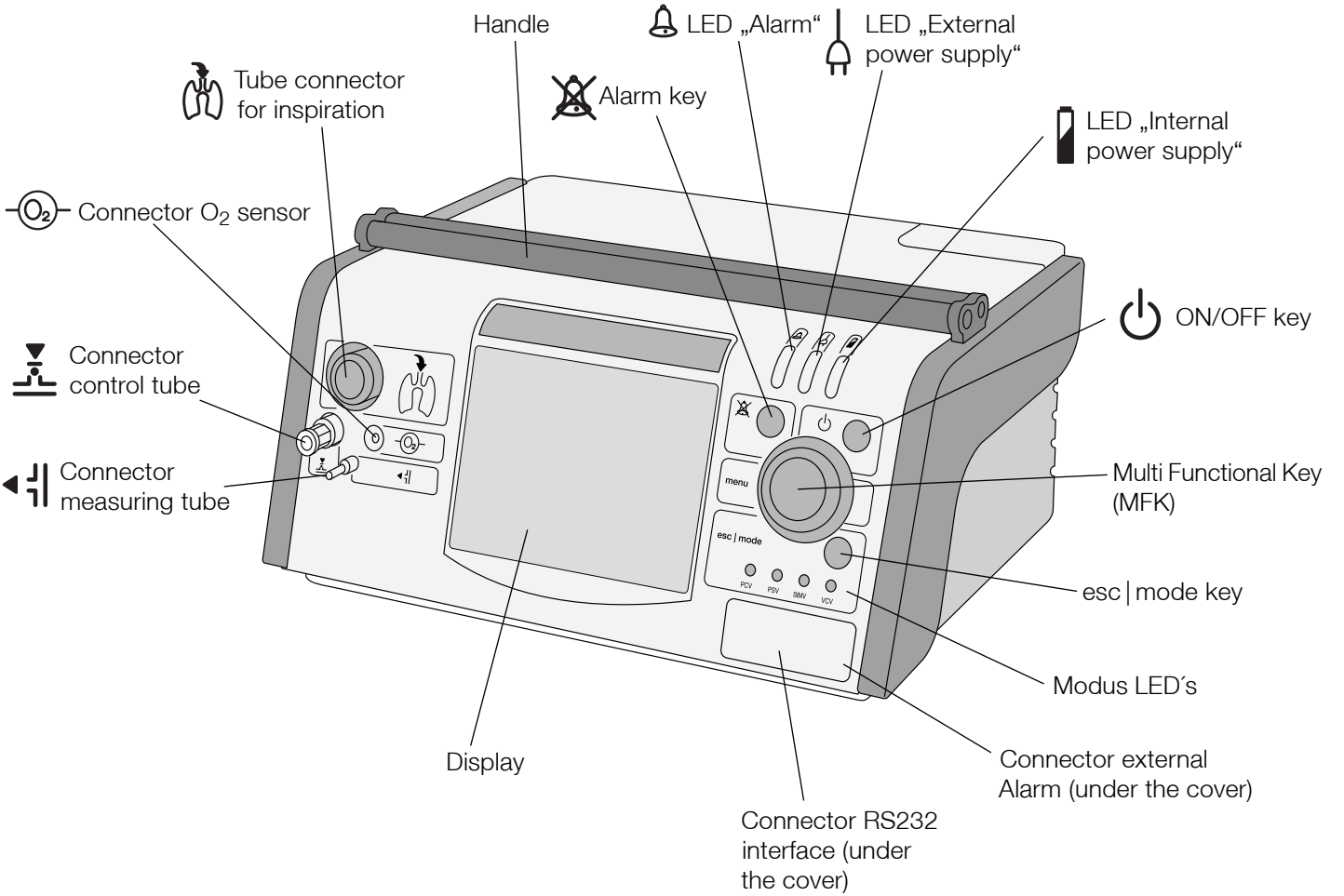


Figure 1: Ventilator front view

BACK VIEW

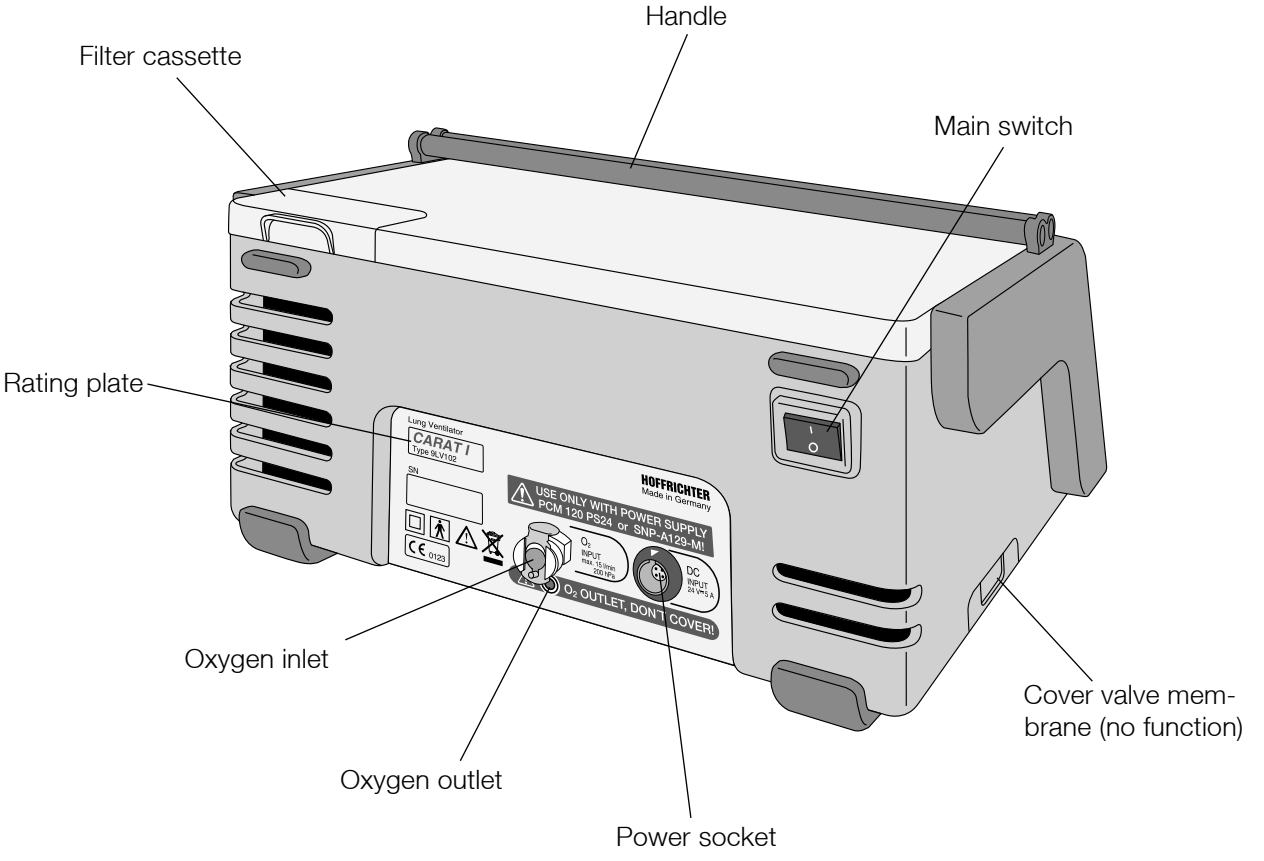


Figure 2: Ventilator back view

DISPLAYS

DISPLAY LAYOUT

CARAT I is provided with a Standard display which is activated in the normal and standby modes of the ventilator as well as with a display of Extended Parameters, a Service display and a display Real Time Monitoring.

While parameter selection is inactive, you can select the displays in the following order by pressing and holding the multi functional key (MFK) for > 1.5 sec:

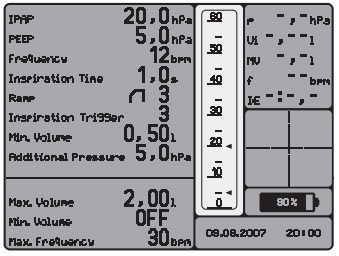
- Standard display
- Display of Extended Parameters
- Service display
- Display Real Time Monitoring
- Standard display

The display of Extended Parameters and the Service display will be left automatically after 30 seconds without any entry and change to the Standard display. The display Real time Monitoring will be left automatically only in case if an alarm occurs. These displays can be closed manually by pressing the esc | mode key.
The left-hand side of the displays differ in their function and displays.

→ see page 24 to page 29

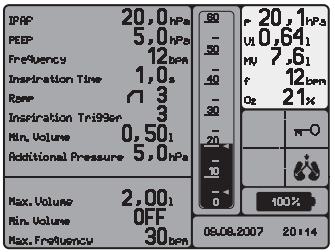
The right-hand side is identical in the Standard display, the display of Extended Parameters and the Service display and is subdivided in the following areas:

- Pressure bargraph
- Actual values
- Symbol field
- Remaining battery capacity
- Text indication field



PRESSURE BARGRAPH

The pressure bargraph indicates the pressure course during ventilation. The arrows indicate the set IPAP or PS (upper arrow) and the set PEEP (lower arrow). The currently achieved maximum pressure of the last spontaneous breath is indicated by the peak mark (horizontal bar).



ACTUAL VALUES

The actual values indicate the currently measured values listed below:

- [p] Peak pressure
- [Vi] Inspiration volume of the previous breath
- [MV] Minute volume
- [bpm] Frequency
- [I:E] I:E ratio

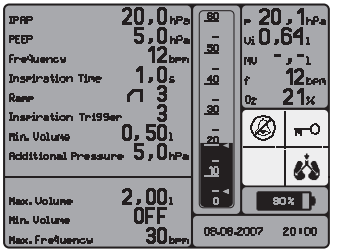
If the device is in stanby mode, the display will show lines.

If the O_2 sensor is connected, the current oxygen content appears instead of the I:E ratio.

SYMBOL FIELD

Acoustic alarm off

This symbol indicates that the acoustic alarm has been muted for 2 min. Any new alarm will also be suppressed acoustically until the 2-min interval has elapsed. By pressing the Alarm key the acoustic alarm can be disactivated before the alarm appears. Pressing the Alarm key again will activate the alarm again.



IMPORTANT

The alarm for “Int. battery discharged” cannot be muted during battery operation.

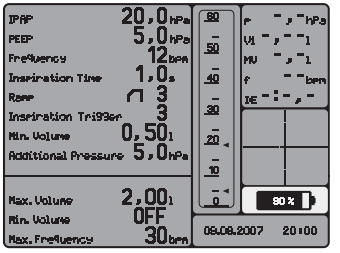
Safety lock

The key signals that the safety lock is activated. A flashing key symbol indicates that disabling/enabling of the safety lock has been activated and must still be confirmed by pressing the MFK. If the safety look is active, all settings on the Standard display and the display of Extended Parameters are disabled. The Service display and the display Real Time Monitoring can not be chosen.

Spontaneous inspiration

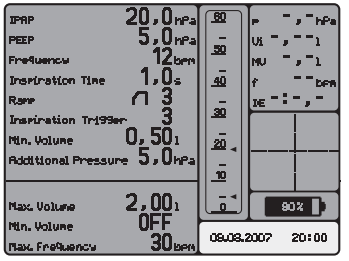
(Initiation of the trigger)

This symbol appears if a spontaneous inspiration was detected. The symbol is displayed for the entire inspiration time and disappears as soon as expiration starts.



REMAINING BATTERY CAPACITY

The battery symbol represents and indicates in percent the remaining capacity of the internal battery. This value is only for reference purposes. To obtain as accurate a value as possible, ventilation should be activated for approx. 1 minute to permit calculation of the battery capacity.
If a DC voltage source is connected to the ventilator, the battery is charged automatically (indicated by a see-saw battery symbol).



TEXT INDICATION FIELD

The text indication field is provided for displaying alarms, messages and device errors in plain text. This display always shows the event having the highest priority. If there are no events, the display shows date and time.

STANDARD DISPLAY

The Standard display is intended for displaying and changing the most important ventilation and alarm parameters which are always based on the ventilation mode currently selected.

→ see section “Ventilation Modes” and section “Alarm Parameters”

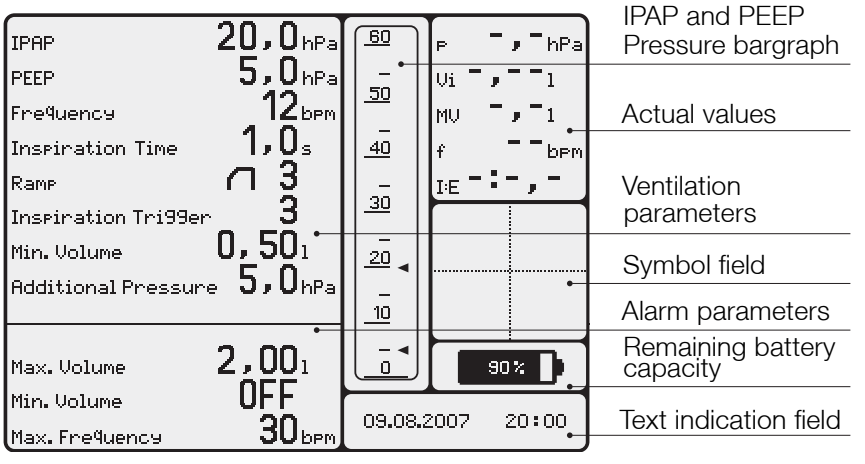


Figure 3: Standard display in the PCV mode

DISPLAY OF EXTENDED PARAMETERS

On the display of Extended Parameters, additional presetting can be made for the ventilator. This display also displays the alarm limits which are independent of the ventilation mode and can be changed.

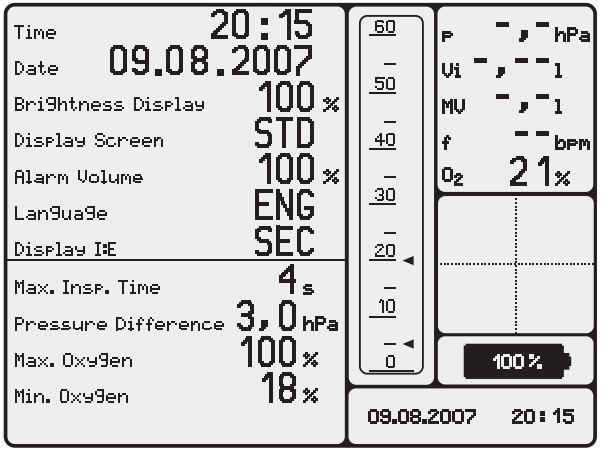


Figure 4: Display of Extended Parameters for all respiration modes, if the O_2 sensor is connected

TIME

Use this menu item to update the time.

DATE

Use this menu item to set the date.

BRIGHTNESS DISPLAY

The display brightness relates to the backlighting in the dark state and can be set to values ranging from 0 to 100 %. The backlighting will always be automatically darkened to this value whenever none of the control elements has been actuated and/or an event has not been detected during ventilation for 30 seconds. As soon as a ventilation alarm occurs or a control element is actuated, the brightness will be automatically set to 100 %.

DISPLAY SCREEN

Using this menu item, it can be selected one of the following screens, which are displayed while ventilation is in progress and backlighting is darkened:

Standard screen (STD)

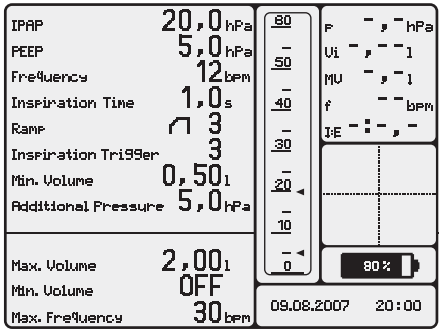


Figure 5: Standard screen (STD)

XXL screen (XXL)

Screen displaying the actual values in enlarged size, but not displaying the setting parameters - appropriately used in hospitals.

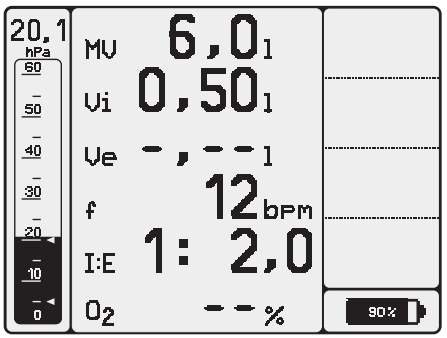


Figure 6: XXL screen

Patient screen (PAT)

Screen displaying minimum information without actual values, nor displaying the setting parameters - appropriately used in home care.

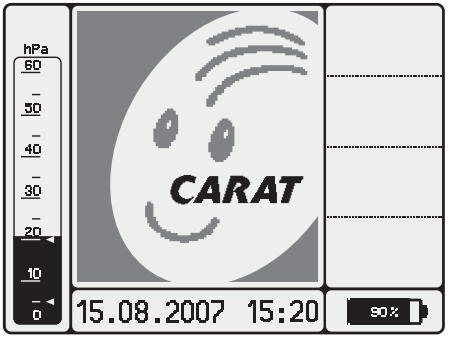


Figure 7: Patient screen (PAT)

ALARM VOLUME

The alarm volume can be set to values ranging from 10 to 100 %, In increments of 10 %.

DISPLAY I:E

Using this menu item, it can be selected whether the ventilation parameter to be set and displayed (in the PCV and VCV modes) is the inspiration time in seconds or the I:E ratio.

LANGUAGE

The device has one of two available language packets.

Language packet 1 contains the languages:
German (DEU), English (ENG), French (FRA), Italian (ITA), Polish (PLK) and Turkish (TUR)

Language packet 2 contains the languages:
German (DEU), English (ENG), French (FRA) and Spanish (SPA)

Further languages are under preparation.

EXTENDED ALARM PARAMETERS

The following alarm parameters can be set in the display of Extended Parameters:

Alarm parameter	Adjustment range	Settings steps	Accuracy
Max. Insp. Time [1]	1 - 10 sec	1.0 s	1.0 s
Pressure Difference	1 - 10 hPa	0.5 hPa	0.1 hPa
Max. Oxygen [2]	OFF, 30 - 100 %	1.0 %	0.3 %
Min. Oxygen [2]	OFF, 18 - 90 %	1.0 %	0.3 %

[1] not applicable to PCV and VCV modes
[2] adjustable only with connected O_2 sensor

STANDARD VALUES IN DISPLAY EXTENDED ALARMS

Brightness Display	100 %
Display Screen	STD
Alarm Volume	50 %
Display I:E	I:E
Leakage	OFF
Max. Insp. Time	4 sec
Pressure Difference	3.0 hPa
Min. Oxygen	OFF
Max. Oxygen	OFF

SERVICE DISPLAY

The service display contains information on the serial number and the software version of the device. In addition, the number of therapy hours, operating hours and respiration hours are indicated. The respiration hours can be deleted menu-driven by pressing the MFK. The last 15 alarms can be read out of the alarm storage. The respective values measured at the time of the alarm are indicated in the actual value screen. This function can only be used in standby operation. In addition to this, the service screen offers the authorized service personnel the possibility of executing various tests and calibrations on the CARAT I.

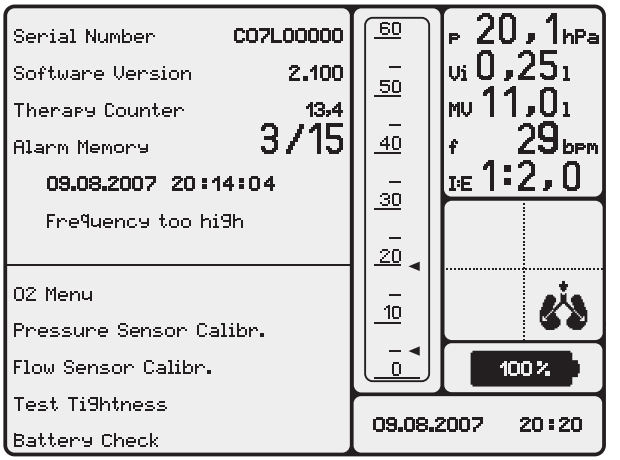


Figure 8: Service screen

DISPLAY REAL TIME MONITORING

The display Real Time Monitoring shows during running ventilation pressure-, flow- and volume curves in real time. The current position of the curves is shown by arrows (▲ ▼) in the upper and lower border of the display. Spontaneous inspiration is symbolized by an arrow (▼) in the upper position, which will stay until the next cycle of curves (Figure 9).

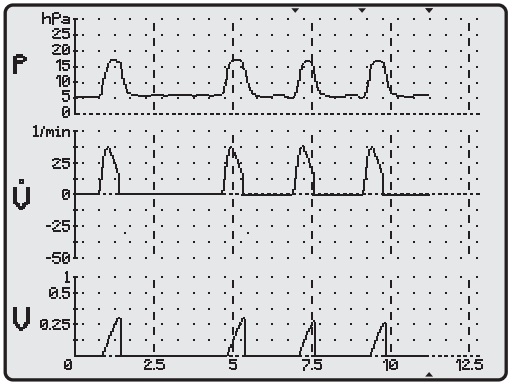


Figure 9: Display Real Time Monitoring PSV-Mode

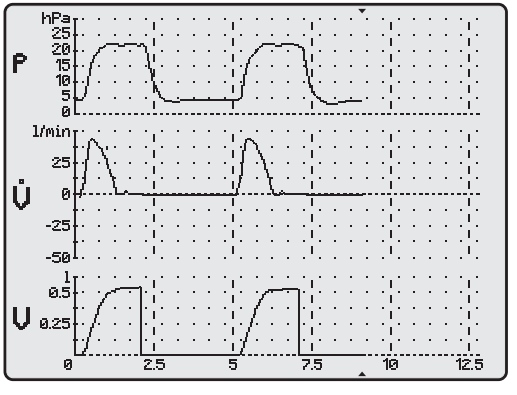


Figure 10: Display Real Time Monitoring PCV-Mode

The current display can be frozen by pressing the multi functional key. Pressing again the multi functional key the real time monitoring will continue with the next inspiration.

The scaling of the curves and the time axis can be changed. To change the scaling, select the symbol by turning the MFK and confirm the selection by pressing the MFK. The maximum value and the unit will be marked. The scaling can be changed by turning the MFK and the picture will be built-on newly. If the scaling was chosen to small, the curves will be displayed just to the boundary value.

	Scaling	Resolution
Pressure	0 – 60 hPa	1.0 hPa
	0 – 30 hPa	0.5 hPa
Flow	- 200 – 200 l/min	5.0 l/min
	- 100 – 100 l/min	2.5 l/min
	- 50 – 50 l/min	1.25 l/min
Volume	0 – 2.5 l	0.05 l
	0 – 1.25 l	0.025 l
	0 – 0.625 l	0.0125 l
Time	0 – 12.5 sec	0.05 sec
	0 – 25 sec	0.1 sec
	0 – 50 sec	0.2 sec

TECHNOLOGY OF THE DEVICE

MAIN ASSEMBLIES

The CARAT I ventilator consists of the following assemblies::

- Blower
- Pneumatic block
- Power supply (internal battery, switched-mode power supply unit)
- Power management
- Controller (control and operating unit)
- External interfaces

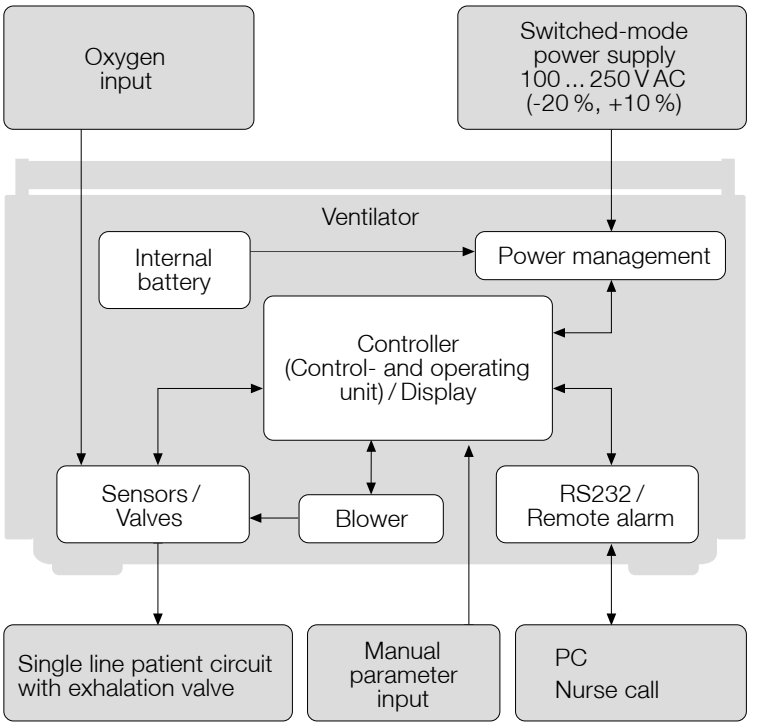


Figure 11: Block diagram of the overall system

Blower

The blower is installed in a sound-absorbing box and delivers a maximum pressure of 50 hPa with a flow of 250 l/min. On its air inlet side, the blower is provided with an air filter cassette with a coarse filter and a fine filter (micro filter / ultra filter).

Power management

The power management permits selection of the operating voltage (DC or battery) as well as on and off monitoring. The value of the motor current depends on the set pressure and flow. The charging current for the internal battery is limited to a battery charging current of 1.0 A. The power management is also intended for displaying the current operating state, i.e. operation by battery or external power supply. In addition, it determines the capacity and the charging state of the internal battery. The data of the battery are transferred to the processor for display purposes.

Power supply

Power is supplied either via an AC/DC switched-mode power supply unit (PCM120 PS24 or SNPA129-M) or by the internal battery. The switched-mode power supply unit has a wide-range input of 100 - 250 V AC (-20 %, +10 %) at 50/60 Hz. The output voltage is 24 V / 5 A.

The internal battery is a lithium-ion battery with a nominal voltage of 28.8 V and a capacity of 2.25 Ah.

Also the external AKKUPACK CARAT can be used as power supply (please ask your local after sales service).

Pneumatic block

The pneumatic block is the connection assembly for the single line patient circuit and consists of the following units:

- Inspiration unit with flow sensor, check valve and standardized tube connector (M 22)
- Pressure connection port (ø = 3.5 mm)
- Connection valve control with quick coupling (SMM 02)
- Oxygen supply with oxygen block including valve and automatically controlled connection
- Valve control with proportional valve and pneumatic inspiration valve

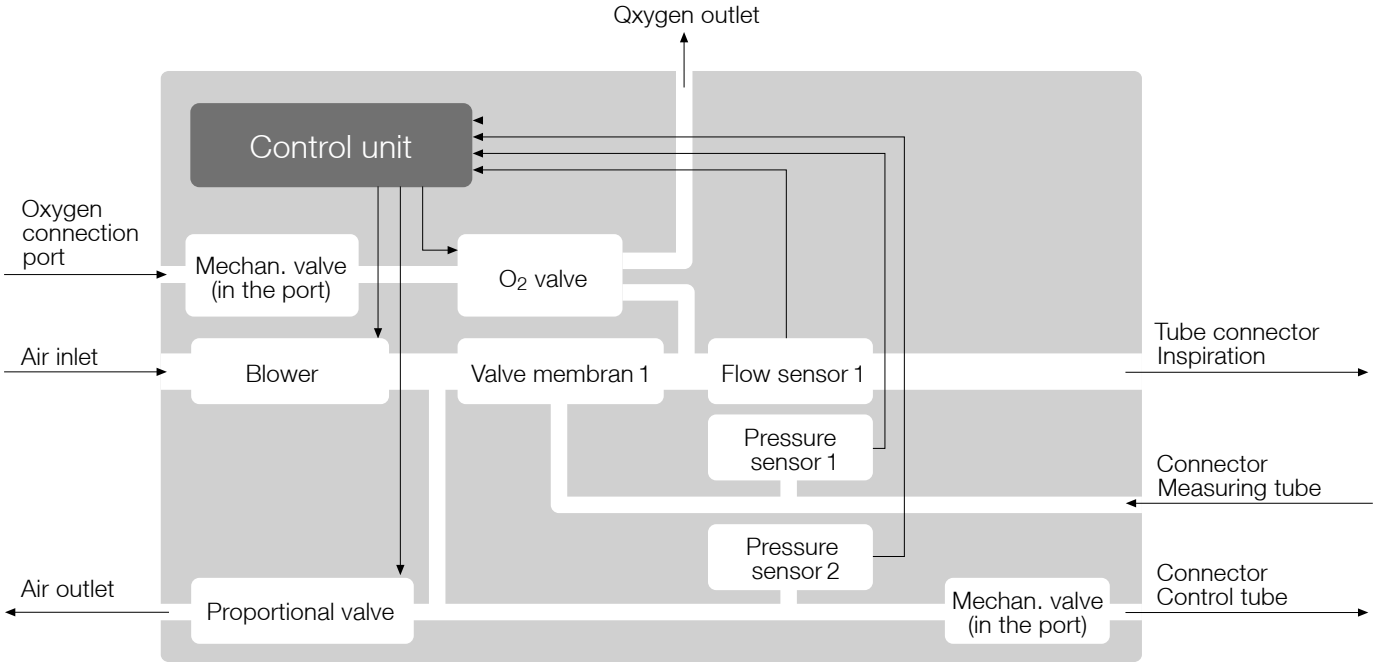


Figure 12: Block diagram of the pneumatic block

Controller (control and operating unit)

The control unit controls the blower and the valves, in order to implement the ventilation modes set. The control unit is also provided for the detection of alarm situations. In addition, the control unit exchanges data with the operating controller and the power management.
Using the operating unit, you can select and display the ventilation modes; the operating unit also allows entering the ventilation parameters by means of the multi functional key and showing the ventilation parameters on the LC display. Ventilation is started via the operating unit. The set ventilation parameters and the associated alarms are saved and the alarms are shown on the display as well as indicated by LED. The operating assembly is provided with a real time clock. It communicates with the external RS232 interface and the remote alarm as well as with the controller via the serial interface. The monochrome display is a 1/4“ VGA screen, which is 320 x 240 mm in size.

Interfaces

The system is provided with a serial interface for the PC software Carat-Control and for software updates. It is also provided with a port for the nurse call or a remote alarm box.

FUNCTIONAL DESCRIPTION

The operating principle of the CARAT I ventilator is based on a control mechanism which, in a closed control loop, adjusts the capacity of the blower to the air output required for therapy. The blower output is controlled by the signal of the airway pressure and by the signal of the inspiration flow.

System start (initialization)

When the system is started, the parameters are read from the memory (EEPROM) and checked for validity. In addition, the pressure and flow sensors as well as the acoustic signal generator are tested. In the event of an error, the error detection is saved and output.
The calibration data is downloaded from the EEPROM and checked for validity. If connected, the oxygen sensor is calibrated against ambient air.

Measurement of parameters

The analogue measurement values of the system are read in and evaluated. Target values are calculated on the basis of the set parameters and/or ventilation modes. Then the target values are transferred to the motor control via a digital-to-analogue converter (DAC).
The proximal pressure and the valve control pressure as well as the inspiration flow are measured.
This data is taken to calculate the inspiration volume and the frequency. In addition, the actual patient flow is determined by calculating the leakage flow. If an oxygen sensor is installed, the oxygen content of the inspiration air FiO_2 is measured.
Pressure or flow sensors detect the patient's spontaneous breathing and initiate the triggers; mask leakages are compensated. The trigger sensitivities can be adjusted. A pressure trigger is used for inspiration. The expiration trigger is a flow trigger and is set in percent of the maximum inspiration flow.

Alarms

Alarm conditions are continuously checked. If occurring, an alarm is indicated by an acoustic and a visual signal. As soon as the alarm condition is eliminated, the acoustical signal is turned off; the visual alarm is still shown on the display until it is acknowledged. In doing so, the cause of the alarm, the settings of the device, the time of the alarm and the current measured values at the time of the alarm are stored. The display of the device allows reading up to 15 alarms.
The alarms are saved in the system and can be read via the PC software. The alarm cause, the device settings and the alarm time are saved. Moreover, the pressure and the flow curves are displayed from 1 min before until 1 min after the alarm.
It is also possible to output alarms of medium and high priority via the remote-alarm function.

Operation during power failure

IMPORTANT

During a power failure, the battery capacity display must be monitored and an alternative power source kept ready. For further details on the display of the battery capacity, please refer to page 78.

When the power supply is interrupted by a power failure, the device is supplied with power via the internal battery. The switch to the internal battery is indicated by an alarm sound, as well as by the text display “Battery Operation”. In addition, the “Alarm” LED and the “Internal power supply” LED are lit. Pressing the alarm button switches the alarm off and switches the text display to date and time.
When the mains power supply returns, the device is supplied with power from the mains supply and the internal battery is charged. The “Internal power supply” LED goes out and the “External power supply” LED is lit.

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VENTILATION MODES

PCV MODE

PCV - Pressure Controlled Ventilation

Pressure controlled or pressure controlled assisted ventilation

Pressure controlled ventilation

In this ventilation mode, ventilation is exclusively controlled by the device. Spontaneous breathing on the patient's part is not possible. To ensure exclusively controlled ventilation, the inspiration trigger must be set to "OFF". The ventilatory period is based on the set frequency and requires a defined I:E ratio. The inspiratory pressure (IPAP) as well as the end-expiratory pressure (PEEP) defines the range of pressure for ventilating the patient. The rise in pressure can be selected by setting a ramp defining the course of the flow curve. The inspiration volume is automatically adjusted to the lung's condition (compliance and resistance). To ensure a minimum volume, it is possible to specify a value and to optionally increase the pressure (IPAP + pressure addition) to reach this minimum volume.

Pressure controlled assisted ventilation

In its ventilation parameters, the pressure controlled assisted ventilation is equal to the exclusively controlled ventilation. By setting an inspiration trigger, however, the patient can stop expiration by inspiration efforts once he reaches the trigger threshold and initiate the next inspiration phase. As in the case with exclusively controlled ventilation, these additional respiratory strokes are only controlled by the device. The inspiration time is defined. The patient can only shorten the expiration time by his own breathing efforts, thus increasing the set frequency rate.

In the PCV mode, the alarm parameters that can be set are the maximum and minimum volumes as well as the maximum frequency. In the assisted ventilation mode, it is particularly important to define the maximum frequency, because the patient may increase the frequency by his own breathing efforts.

PSV MODE

PSV - Pressure Supported Ventilation

Pressure supported ventilation is intended to support spontaneous breathing and to initiate machine ventilation whenever spontaneous breathing is missing. The pressure support (PS) as well as the positive end-expiratory pressure (PEEP) defines the range of pressure for ventilating the patient. The trigger thresholds of the inspiration trigger and the expiration trigger can be adjusted to the patient's requirements. The adjustable frequency is set in the background. As long as the patient reaches or exceeds this frequency by spontaneous breathing, the ventilator reacts with the pressure support to each spontaneous inspiration, following the patient's breathing. If the background frequency fails to be reached, the device assumes machine ventilation until it registers the next spontaneous breath. To permit respiratory pauses between the patient's breathing efforts, an apnea limit can be set to delay the start of the ventilator strokes. The rise in pressure between PEEP and PS can be selected by setting a ramp which defines the course of the flow curve. The tidal volume is automatically adjusted to the lung's condition (compliance and resistance). To ensure a minimum volume, it is possible to specify a value and to optionally increase the pressure (PS + Additional Pressure) to reach this minimum volume.

In the PSV mode, the alarm parameters that can be set are the maximum and minimum volumes as well as the maximum frequency.

In PSV mode the frequency and the apnea limit (because of the dependence both synchronously) can be "OFF". At this setting the following message appears in the Text Indication Field: PSV-S

IMPORTANT

With this setting the device only reacts on existing spontaneous breathing of the patient.

SIMV MODE

SIMV - Synchronous Intermittent Mandatory Ventilation

The SIMV mode provides a combination of pressure controlled machine ventilation and pressure assisted spontaneous breathing.
Machine ventilation is based on a defined respiratory rate (SIMV frequency) and a defined inspiration time. The inspiratory pressure (IPAP) as well as the end-expiratory pressure (PEEP) defines the range of pressure for ventilating the patient. The rise in pressure can be selected by setting a ramp defining the course of the flow curve. The inspiration volume is automatically adjusted to the lung's condition (compliance and resistance). The patient cannot manipulate these ventilator strokes by his own ventilatory drive. Only their beginning is adjusted to spontaneous breathing, if necessary. Spontaneous breathing on the patient's part is possible between the ventilator strokes if the trigger thresholds for inspiration and expiration triggers are reached. During inspiration, spontaneous breathing is supported by a pressure (PS) that can be selected beforehand and is independent of the IPAP. The length of the spontaneous breaths and the inspiration time are exclusively defined by the patient. The ventilator strokes are adjusted to spontaneous breathing in terms of time. If, for example, a spontaneous inspiration occurs shortly before a SIMV period is started (within a specific expected time window = 2 seconds), the device initiates the ventilator stroke synchronously with the patient's own breathing already at that time.

In the SIMV mode, the alarm parameters that can be set are the maximum and minimum volumes as well as the maximum frequency.

VCV MODE

VCV - Volume Controlled Ventilation

Volume controlled ventilation or volume controlled assisted ventilation

Volume controlled ventilation

In this ventilation mode, ventilation is exclusively controlled by the system. Spontaneous breathing on the patient's part is not possible. To ensure exclusively controlled ventilation, the inspiration trigger must be set to "OFF". The ventilatory period is based on the set respiratory rate and requires a defined I:E ratio. The inspiration volume is defined such that the corresponding pressure is based on the condition of the lung (compliance and resistance). It is also possible to set the positive endexpiratory pressure (PEEP). The inspiration flow (ramp) can be selected as constant flow or as decelerating flow.

Volume controlled assisted ventilation

In its ventilation parameters, the volume controlled assisted ventilation is equal to the exclusively controlled ventilation. By setting an inspiration trigger, however, the patient can stop expiration by inspiration efforts once he reaches the trigger threshold and initiate the additional respiratory strokes. As is the case with exclusively controlled ventilation, these additional respiratory strokes are only controlled by the device. The inspiration time is defined. The patient can only shorten the expiration time by his own breathing efforts, thus increasing the set frequency.

In the VCV mode, the alarm parameters that can be set are the maximum and minimum pressures. It is also possible to set the maximum frequency. In the assisted ventilation mode, it is particularly important to define the maximum frequency, because the patient may increase the frequency by his own breathing efforts.

PARAMETERS

VENTILATION PARAMETERS

VENTILATION PARAMETERS ON THE “STANDARD DISPLAY”

The ventilation parameters listed below are displayed on the left-hand side of the Standard display and can be changed within the appropriate adjustment ranges. The particular display of the changeable parameters depends on the ventilation mode selected.
The pressure unit can be converted from hPa to cm H_2O or mbar by using the PC software.

SETTINGS IN THE PCV MODE

Parameter	Adjustment range	Settings steps	Accuracy
IPAP	4 to 50 hPa	0.5 hPa	0.1 hPa
PEEP	0 to 20 hPa [PEEP ≤ IPAP – 3 hPa]	0.5 hPa	0.1 hPa
Frequency	4 to 50 bpm	1 bpm	1 bpm
Inspiration Time	0.3 to 8.0 sec	0.1 sec	0.1 sec
I:E	1:0.3 to 1:4.0	0.1	0.1
Ramp	stage 1 to stage 5	1 stage	1 stage
Inspiration Trigger	OFF; stage 1 to stage 5; AUTO	1 stage	1 stage
Minimum Volume	OFF; 0.05 to 2 l [if IPAP > 47 hPa, then always OFF]	0.01 l	0.01 l
Additional Pressure	3 to 10 hPa [Additional Pressure ≤ 50 hPa – IPAP]	0.5 hPa	0.1 hPa

SETTINGS IN THE PSV MODE

Parameter	Adjustment range	Settings steps	Accuracy
PS	4 to 50 hPa	0.5 hPa	0.1 hPa
PEEP	0 to 20 hPa [PEEP ≤ PS – 3 hPa]	0.5 hPa	0.1 hPa
Frequency	4 to 50 bpm; OFF	1 bpm	1 bpm
Apnea Limit	AUTO; 3 to 60 sec; OFF	1 sec	1 sec
Ramp	stage 1 to stage 5	1 stage	1 stage
Inspiration Trigger	stage 1 to stage 5; AUTO	1 stage	1 stage
Minimum Volume	OFF; 0.05 to 2 l [if PS > 47 hPa, then always OFF]	0.01 l	0.01 l
Additional Pressure	3 to 10 hPa [Additional Pressure ≤ 50 hPa – PS]	0.5 hPa	0.1 hPa

IMPORTANT

If the apnea limit is set to a value > 15 sec, a corresponding message has to be confirmed.

If frequency e.g. apnea limit is set to OFF, the device works in PSV-S mode and only reacts on spontaneous breathing of the patient.

SETTINGS IN THE SIMV MODE

Parameter	Adjustment range	Settings steps	Accuracy
IPAP	4 to 50 hPa	0.5 hPa	0.1 hPa
PS	4 to 50 hPa	0.5 hPa	0.1 hPa
PEEP	0 to 20 hPa [PEEP < IPAP / PS – 3 hPa]	0.5 hPa	0.1 hPa
SIMV Frequency	4 to 50 bpm	1 bpm	1 bpm
Inspiration Time	0.3 to 8.0 sec	0.1 sec	0.1 sec
Ramp	stage 1 to stage 5	1 stage	1 stage
Inspiration Trigger	stage 1 to stage 5; AUTO	1 stage	1 stage
Expiration Trigger	AUTO; 10 to 90 %	10 %	1 %

SETTINGS IN THE VCV MODE

Parameter	Adjustment range	Settings steps	Accuracy
Volumen	0.05 to 2 l [V < 1,5 l/sec x Insp. time]	0.01 l	0.01 l
PEEP	0 to 20 hPa	0.5 hPa	0.1 hPa
Frequency	4 to 50 bpm	1 bpm	1 bpm
Inspiration Time	0.3 to 8.0 sec	0.1 sec	0.1 sec
I:E	1:0.3 to 1:4.0	0.1	0.1
Ramp	stage 1 - stage 4	1 stage	1 stage
Inspiration Trigger	OFF; stage 1 to stage 5; AUTO	1 stage	1 stage

IMPORTANT

The volume setting is directly connected to the set max. pressure (see page 50). If the “Max. Pressure” selected is too low, there is a possibility that the set volume is not reached. In this case, the “Volume too low” alarm is triggered.

DESCRIPTION OF VENTILATION PARAMETERS

IPAP

IPAP (= Inspiratory Positive Airway Pressure) is the therapeutically pressure in the PCV and SIMV modes, which is administered to the patient with each ventilator stroke during inspiration. The set IPAP value is not summed up to the set PEEP, but represents the maximum inspiratory pressure.

PS

PS (= Pressure Support) is the pressure administered to the patient in the PSV mode, which supports the patient in his/her own spontaneous inspiration or the inspiratory pressure which is administered with the ventilator stroke when the patient's own breathing fails. In the SIMV mode, PS is exclusively intended as pressure support of the patient's spontaneous inspiration. The set PS value is not summed up to the set PEEP, but represents the maximum inspiratory pressure.

VOLUME

The volume is the adjustable inspiration volume, which is administered to the patient on each inspiration in the VCV mode.

PEEP

PEEP (= Positive End Expiratory Pressure) is the positive pressure which is available to the patient at the end of each expiration and before a new inspiration, both spontaneously and under ventilator control. PEEP can be set in all ventilation modes.

FREQUENCY / SIMV FREQUENCY

When a frequency is set in the controlled ventilation modes (PCV / VCV), then a defined frequency is specified by a machine. In the PSV mode and in the assisted PCV or VCV mode, the set frequency is defined as the minimum frequency, which can be increased by spontaneous breaths of the patient. In the SIMV mode, the SIMV frequency is defined as the frequency used to supply the ventilator strokes to the patient at the IPAP specified and during the inspiration time specified. Thus, the SIMV frequency ensures the patient's minimum frequency.

In between the ventilator strokes, the patient can increase his/her frequency by means of spontaneous inspiration.

APNEA LIMIT

In the PSV mode, an apnea limit can be set if it is intended to permit respiratory pauses between the patient's spontaneous breathing efforts. The apnea limit serves to set the delay time which, after having elapsed, will initiate ventilator strokes in the event of respiratory pauses. If the apnea limit is set to AUTO, the ventilator strokes are initiated without delay, according to the set frequency.

INSPIRATION TIME / I:E

The inspiration time or I:E ratio can be set in the PCV and VCV modes. The Display of Extended Parameters provides the option of selecting adjustment of either the inspiration time or the I:E ratio. In the SIMV mode, the inspiration time is the only adjustable parameter. The inspiration time defines the duration of inspiration (in seconds). When setting this parameter, the frequency selected must be taken into consideration. If a defined inspiration time is set, the I:E ratio is calculated in relation to the frequency.

The I:E ratio is the ratio of inspiration to expiration content in the total respiratory cycle. If a defined I:E ratio is set, the inspiration time depends on the currently set frequency.

PCV / PSV /SIMV

In the pressure controlled ventilation modes, the ramp settings limit the increase in pressure in the inspiration phase. This pressure increase is not set as a time parameter, but is implemented by setting the course of the flow curve in the inspiration phase, i.e. by limiting the flow increase. The resistance and the compliance of the patient's lungs are also taken into consideration so that the varying conditions of different patients' lungs will also result in varying pressure increase times. When setting an individual ramp, the currently specified inspiration time in which the increase in pressure should be reached must be taken into consideration.

For example, the following table provides an overview of the change in the pressure increase time with various ramp settings in case of a healthy lung:

Ramp setting	Pressure increase time
1	1.7 sec [1]
2	1.0 sec [1]
3	0.6 sec [1]
4	0.4 sec [1]
5	0.3 sec [1]

Figure 13: Pressure increase time in seconds with an IPAP of 20 hPa and a PEEPof 5 hPa

[1] The values specified are reference times and vary in relation to the pressure range set and to the condition of the patient's lung.

VCV

While setting the ramp in the volume controlled mode, the course of the inspiration flow can be selected as constant flow (stage 1) or as decelerating flow (stage 2 - 4).

INSPIRATION TRIGGER

The inspiration trigger specifies the extent of the patient's inspiration efforts required to obtain pressure or volume support from the ventilator in case of spontaneous breathing.

Pressure trigger

If a single line patient circuit is used, the pressure trigger is activated. An inspiration is triggered when the patient generates a certain negative pressure in the tubing system by his/her own inhalation efforts, i.e. when the pressure has dropped by the currently set value. In addition, it will be checked it there is a positive flow.

Trigger stage	Pressure trigger
1	0.2 hPa
2	0.5 hPa
3	0.8 hPa
4	1.0 hPa
5	1.5 hPa

IMPORTANT

Please always take utmost care and always consider the patient's clinical picture when setting the trigger stages, in order to prevent the risk of auto triggering.

Automatic trigger

The automatic trigger can be activated independently from the selection of the tube system. If the setting "AUTO" has been selected, the device calculates the proper time of triggering from a combination of volume and flow trigger on its own and starts the inspiration.

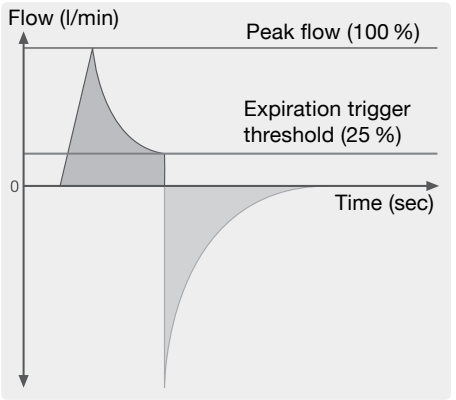


Figure 14: Respiratory curve with peak flow and trigger threshold

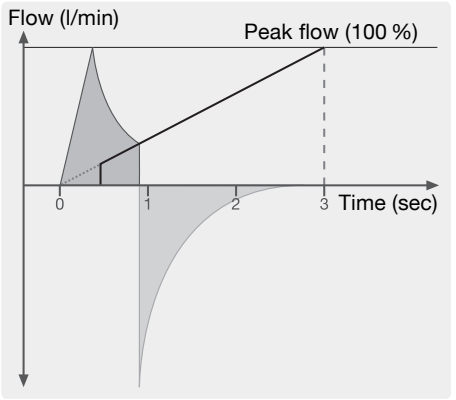


Figure 15: Respiratory curve with peak flow and automatic trigger

EXPIRATION TRIGGER

The expiration trigger is a flow trigger. The peak flow of the inspiration is measured with each breath. The setting of the expiration trigger defines the percentage of the peak flow at which the ventilator switches over to expiration.
When “AUTO” is set, the retrigger threshold is determined dynamically depending from the duration of the inspiration. For this purpose, the maximum flow during the inspiration is also analysed. The threshold increases proportionately to the inspiration duration and corresponds after 3 sec to 100 % of the maximum inspiration flow (i.e. 33 % after 1 sec, 66 % after 2 sec, etc). Should the current flow fall below this threshold, a switching to expiration takes place.

MINIMUM VOLUME

In the PCV and PSV modes, it is possible to set a minimum tidal volume intended to ensure the necessary volume during pressure controlled ventilation.

ADDITIONAL PRESSURE

To ensure the minimum volume, it is possible to specify an additional pressure which can be added to the IPAP or PS pressure if the minimum volume fails to be reached. The value of the set additional pressure is a maximum value. In order to calculate the actually required additional pressure, the minimum volume is set in relation to the actual volume and the necessary inspiratory pressure is calculated from the current inspiratory pressure. On the one hand, the increase in pressure is limited by the set additional pressure as a maximum value; on the other hand, it is limited by a maximum additional pressure of 2 hPa as compared with the inspiratory pressure of the previous breath.

ALARM PARAMETERS

ALARM PARAMETERS ON THE “STANDARD DISPLAY”

The alarm parameters listed below are displayed on the left-hand side of the Standard display and can be changed within the appropriate adjustment ranges. The particular display of the changeable parameters depends on the ventilation mode selected.

SETTINGS IN THE PCV, PSV AND SIMV MODES

Alarm parameter	Adjustment range	Settings steps	Accuracy
Max. Volume	OFF; 0.20 to 2.50 l	0.01 l	0.01 l
Min. Volume	OFF; 0.01 to 2.00 l [Min. Volume ≤ Max. Volume – 0.1 l]	0.01 l	0.01 l
Max. Frequency PCV/SIMV	OFF; 10 to 120 bpm [Max. Frequency ≥ Frequency + 5 bpm]	1 bpm	1 bpm

SETTINGS IN THE VCV MODE

Alarm parameter	Adjustment range	Settings steps	Accuracy
Max. Pressure	11 to 50 hPa [Max. Pressure ≥ PEEP + 3 hPa]	0.5 hPa	0.1 hPa
Min. Pressure	2 to 40 hPa [Min. Pressure ≥ PEEP + 2 hPa, Min. Pressure < Max. Pressure]	0.5 hPa	0.1 hPa
Max. Frequency	OFF; 10 to 120 bpm [Max. Frequency ≥ Frequency + 5 bpm]	1 bpm	1 bpm

IMPORTANT

The “Max. Pressure” setting limits the upward pressure and influences the “Volume” setting (see page 44).

ALARM PARAMETERS ON THE “DISPLAY OF EXTENDED PARAMETERS”

The alarm parameters listed below are displayed in the left lower area of the display of Extended Parameters and can be changed within the appropriate adjustment ranges. These parameters are displayed independently of the ventilation mode selected.

→ see section “Display of Extended Parameters”

Alarm parameter	Adjustment range	Settings steps	Accuracy
Max. Insp. Time [only applies in the PSV mode and during spontaneous respiration in the SIMV mode]	1 to 10 sec	1 sec	1 sec
Pressure Difference	1 to 10 hPa	0.5 hPa	0.1 hPa
Max. Oxygen [adjustable only with connected O_2 sensor]	OFF; 30 to 100 %	1 %	0.3 %
Min. Oxygen [adjustable only with connected O_2 sensor]	OFF; 18 to 90 % [Min. Oxygen ≤ Max. Oxygen – 10 %]	1 %	0.3 %

COMMISSIONING

IMPORTANT

Prior to operating the device for the first time and whenever the patient is exchanged, a functional check must be performed (see section “Functional Check”).
Before commissioning the ventilation system (ventilator, tube, humidifier, etc.), check all connections for leaks, as well as the stability of the connected accessories.

SETTING UP THE VENTILATOR

Place the ventilator on a plane and stable surface. The ventilator can also be operated in any other position, in which case the air inlet must be reliably prevented from getting blocked.

USING THE FUNCTIONAL BAG (OPTIONAL ACCESSORY)

IMPORTANT

When using the device in the functional bag, the following advice should be noted for safe and error-free operation.

Set the alarm sound to 100 % volume. Make sure that all necessary alarm messages can be read through the viewing window and that the bag’s ventilation openings are not blocked. The air supply for the device must be guaranteed at all times.
Use the bag in such a way that the device is protected from overheating, dust and water. All accessories connected, such as tube, filter, supply lines, etc, must be arranged such that they cannot lead to any impedance or malfunction of the device.

POWER SUPPLY

To operate the CARAT I with external power supply, connect the supplied power supply unit to the DC socket on the rear of the ventilator and to the power cord. Then connect the ventilator to a 100 - 250 V AC (-20 % / +10 %), 50 - 60 Hz voltage source via the mains cable.

CONNECTING A SINGLE LINE PATIENT CIRCUIT

IMPORTANT

When a nasal or full face mask is used for noninvasive ventilation, this mask must not contain any expiration opening.

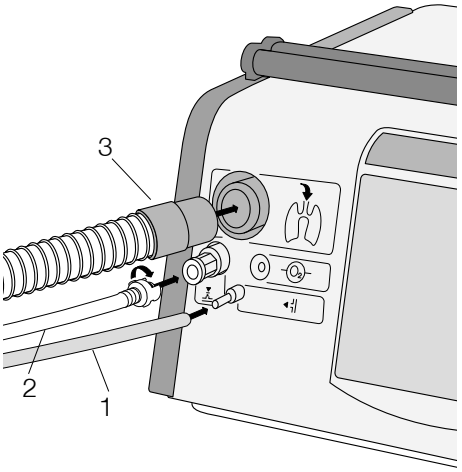


Figure 16: Connecting a Single Line Patient Circuit

1. Connect the measuring tube to the connector measuring tube ( ) on the device.
2. Connect the control tube for the expiration valve to the connector control tube ( ) on the device (SMM 02).
3. Connect the therapy tube of the single line patient circuit to the tube connector for inspiration ( ) on the device (FM 22).

TURNING THE VENTILATOR ON

IMPORTANT

An acoustic signal must be generated when the device is switched on. If this is not the case, the device must not be used and should be checked by an authorized service technician.

If there is a big difference between the temperature at the place of use of the ventilator and the temperature at the place where the ventilator was positioned before, then half an hour must elapse before the ventilator is put into operation, in order to allow the temperature to compensate.

On device start, the patient circuit may already be connected to the ventilator, but not to the patient yet.

Turn the CARAT I ventilator on via the main switch on the rear of the system. It will then emit an acoustic signal tone. The display of the ventilator indicates the serial number, the software version, the therapy counter and the operation hours. The device performs an internal hardware test and checks the parameters for plausibility. If the hardware test is completed successfully, the device automatically displays the Standard screen. If an error is deteted, the appropriate error message is displayed. The device will not return to the Standard screen until this error message is confirmed by pressing the MFK.
If an O_2 measuring cell was connected before the ventilator is turned on, this cell is calibrated automatically during system start. If the ventilator is not connected to external power supply while being turned on, an acoustic signal tone is emitted, accompanied by the message “Battery Operation” in the text indication field. This message has to be confirmed by pressing the Alarm key.

OXYGEN SUPPLY

⚠WARNING
Oxygen may only be supplied if prescribed by a physician. An excessive oxygen supply may result in serious complications for the patient.

- If you supply the patient with oxygen via the ventilator, a FiO_2 measurement should be carried out.
- Please be absolutely sure to observe the instructions for use issued by the manufacturer or dealer delivering the oxygen.
- The CARAT I ventilator allows FiO_2 measurement via the O_2 sensor which is optionally available as an accessory part. We recommend using this O_2 sensor only.
- The oxygen sensor contains a caustic liquid. Avoid skin or eye contact if there is a sensor leak!
- The pressure of the supplied oxygen must not exceed a value of 200 hPa; its flow must not exceed 15 l/min. The oxygen must be metered out via an external flow meter.
- During oxygen supply using the device's O_2 connection, no humid oxygen may be used. Damp air may lead to device defects. If necessary, a humidifier can be connected between the air outlet of the device and the patient.
- The connection between the O_2 connection and external O_2 source must be absolutely airtight. Otherwise, leakage losses may occur during ventilation.

- Oxygen supply should be stopped before the ventilation is interrupted. We also recommend that you run the ventilator without supplying oxygen for several ventilatory periods before starting and after completing the ventilation process.
- In case of an oxygen leak, the oxygen source must be closed on the spot. The room must immediately be ventilated. At the same time, any sparks, fire or potential sources of fire in the vicinity must be avoided.
- Oxygen supports combustion. Therefore, observe the fire protection regulations applicable for using oxygen. Ensure that the oxygen fittings, as well as all ports and surfaces near the oxygen lines are free of grease. Do not smoke and do not handle naked flames. When using oxygen, an increased oxygen concentration in the ambient air can occur.

Oxygen can be supplied in all ventilation modes. The oxygen inlet for external oxygen supply is provided on the rear of the ventilator. The only O_2 adapter type that may be used is the one that is delivered with the ventilator. Otherwise, the return stop in the connection port may be damaged.
Please note that changing the ventilation parameters, such as respiratory pressure, I:E, frequency, will also change the FiO_2 content.

O_2 MEASUREMENT

O_2 measurement is performed with the optionally available O_2 sensor. Fit the sensor in the T-adapter which matches the ventilator and the patient circuit. The T-adapter is provided with a connector (ø = 22 mm) which must be fitted onto the tube connector for inspiration. Insert the O_2 sensor cable into the Connector O_2 sensor on the front of the ventilator and screw on the plug by a clockwise rotation. The O_2 sensor is calibrated automatically on device start. If the sensor is connected at a later point, the text indication field will display the message “Calibrate O_2 sensor”. Calibrate

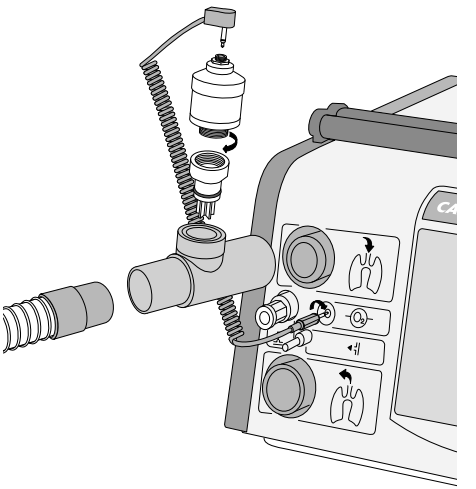


Figure 17: Connecting O_2 sensor

then the sensor in stand-by-mode by selecting “O2 MENU” on the Service display. Calibration is against ambient air, which is assumed to contain 21 % oxygen.
Depending on the ambient conditions, the sensor can require up to 30 minutes after installation to reach signal stability.

The supply of oxygen is possible anytime. The valve for oxygen supply is opened during the running ventilation.

IMPORTANT

Oxygen sensors have a limited durability. A durability of 15 months after the date of manufacture applies for oxygen sensors supplied by HOFFRICHTER. The period of use of the sensors is 6 months. After that, the oxygen sensor must be replaced by a new one. The date of manufacture can be found on the oxygen sensor.
For the longest possible sensor service life, we recommend storage at - 15 °C to + 5 °C.

OPERATION

TURNING THE DEVICE ON AND OFF

Turn the ventilator on and off by actuating the main switch on the rear of the device. After the ventilator has been turned on, the device performs an automatic hardware test.

→ see section “System start (initialization)”

The ventilator can only be switched off, if the respiration has been terminated before. Should the main switch on the backside of the device be set to “0” during an ongoing respiration, a warning pops up reading “Stop Ventilation? Yes/No”. Additionally, an acoustic alarm rings out. If you confirm with “Yes”, the respiration is terminated. If you select “No”, you receive the warning:

The device remains switched on and the respiration is continued. The alarm remains active until the main switch is set back to “I” or the respiration is terminated. If the respiration is terminated and the device is switched off via the main switch, the message appears “Data is being saved Device will be switched off”. After successful data storing, the device switches itself off.

IMPORTANT

If you turn off the ventilator, all parameters set will be preserved.

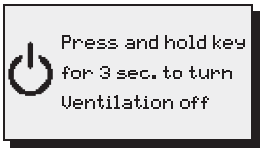
START AND END OF VENTILATION

START OF VENTILATION

Start ventilation by actuating the ON/OFF key. While ventilation is in progress, the actual values indicate all values currently measured.

END OF VENTILATION

After short pressing of the ON/OFF key a signal tone sounds and in the display appears the message:



By pressing of the ON/OFF key for approx. 3 sec the signal tone silences, the display message disappears and the respiration stops. Afterwards, a short signal tone sounds.
If the ON/OFF key will not released the respiration continues.

ENABLING AND DISABLING THE SAFETY LOCK

The CARAT I ventilator is provided with a safety lock as a protection against inadvertent or unauthorized readjustment of the ventilation and alarm parameters. Once the safety lock is enabled, all settings on the Standard display and display of Extended Parameters are disabled. The Service display and the display Real Time Monitoring can not be chosen any longer.

The enabled safety lock is indicated by the key symbol ( ) being shown in the symbol field. The safety lock can only be enabled and disabled if the Standard display is shown.

To enable and disable the safety lock, press and hold the esc | mode key (> 1.5 sec) and then confirm by pressing the MFK while the key symbol is flashing.

An automatic safety lock can be activated via the PC software CaratControl. This safety lock activates automatically, if no button is pushed for 5 minutes.

FUNCTION OF THE esc | mode KEY

The esc | mode key has two functions. On one hand the function “esc” (escape) to cancel unwanted entries, and on the other hand the function “mode” to change ventilation modes.

ESCAPE

By pressing the esc | mode key, not yet confirmed entries can be cancelled. If a parameter is selected and changed but has not yet been confirmed by pressing the MFK, the entry can be cancelled by pressing the esc | mode key. Irrespective of on which display you are, the esc | mode key will always take you back to the standard display. Pressing the esc | mode key while you are in the standard screen will take you to the selection menu of the ventilation modes. If this has happened by mistake, the entry can also here be cancelled by pressing the esc | mode key.

SELECTING THE VENTILATION MODE

CHANGING THE VENTILATION MODE WITH VENTILATION NOT RUNNING

The mode can only be changed if the Standard display is shown and none of the parameters is selected. If necessary, press the esc | mode key. The ventilation mode currently selected is indicated by the appropriate mode LED emitting steady light. By pressing the esc | mode key, the mode menu will open. By turning the MFK the desired ventilation mode can be selected. Confirm the selection by pressing the MFK and the device will switch to the selected mode.

CHANGING THE VENTILATION MODE WITH VENTILATION RUNNING

The mode can only be changed if the Standard display is shown and none of the parameters is selected. If necessary, press the esc | mode key. The ventilation mode currently selected is indicated by the appropriate mode LED emitting steady light. By pressing the esc | mode key, the mode menu will open. By turning the MFK the desired ventilation mode can be selected. Pressing the MFK will confirm preselection of the new mode - the mode LED will continue flashing. Thereafter, the ventilation and alarm parameters can set and/or change of the new mode on the left-hand side of the screen. The old, still activated mode is indicated by the mode LED still emitting steady light. Once the parameters for the new mode are set, turn the MFK to select the “Accept settings” options in the text indication field. Confirm the selection by pressing the MFK. Once the next inspiration is started, ventilation will be continued in the new mode.

CHANGING THE VENTILATION AND ALARM PARAMETERS

To select the appropriate parameter, turn the MFK, irrespective of whether it is a ventilation or an alarm parameter. The parameter currently selected is highlighted by a black bar for 3 seconds. Confirm your selection of this parameter by pressing the MFK. Thereafter, both the parameter and its value are
highlighted by a black bar. To change the parameter value, turn the MFK. If the changed parameter value is associated with one or more dependent parameters which are also changing, then the values of these parameters are highlighted with a black bar as well. To confirm the changed value or the several
changed parameter values, once again press the MFK. After having been confirmed, changed values are applied at once.

IMPORTANT

If a changed parameter value is not confirmed by turning the MFK, the parameter selected will be exited automatically after 30 seconds; the changed value will not be applied.

CHANGING DISPLAYS

The display can only be changed if none of the parameters is selected. If necessary press the esc | mode key.
It can be moved among the displays by pressing and holding the MFK (> 1.5 sec), in the following order:

- Standard display
- Display of Extended Parameters
- Service display
- Display Real Time Monitoring
- Standard display

IMPORTANT

If there is not actuated any control element in the display of Extended Parameters or Service display for 30 seconds, the system automatically returns to the Standard display. The display Real Time Monitoring will be left automatically only if an alarm occurs.

If the safety lock is enabled, the Service display is disabled. In this case, only the Standard display or the display of Extended Parameters can be selected.

FUNCTIONAL ASSIGNMENT OF THE CONTROL ELEMENTS

Control element	Function	Actuation
ON/OFF key	Ventilation on	Press briefly
	Ventilation off	Press and hold (> 3 sec)
Alarm key	Mutes the alarm tone in case of a ventilation alarm	Press briefly
	Acknowledges the ventilation alarm	Press briefly
Multi functional key (MFK)	Selects the parameters	Turn
	Activates the parameters	Press briefly
	Sets the parameters	Turn
	Confirms the parameter selection	Press briefly
	Confirms the changed parameter values	Press briefly
	Changes the screen display	Press and hold (> 1.5 sec)
	“Freezing” and continuing the curve display in the display Real Time Monitoring	Press briefly
esc I mode key	Activates the ventilation mode menu	Press briefly
	Enables and disables the safety interlock	Press and hold (> 1.5 sec)
	Escape from choosen parameters/screens	Press briefly

ALARMS AND ERROR MESSAGES

GENERAL INFORMATION

⚠CAUTION
Alarm limits may only be set by qualified and skilled personnel under the supervision of a physician.

The alarms of the CARAT I ventilator are either defined alarms or alarms that are adjustable in relation to the particular ventilation mode. All of the adjustable alarms are preserved when CARAT I is turned off and will again be active on device restart. All of the alarms and error messages are indicated visually, acoustically and by means of text messages. The acoustic and visual indications vary depending on the priority of the alarm:

- HIGH priority
  10 fast pulses (repeated every 5 sec);
  red flashing at a rate of 2 Hz
- MEDIUM priority
  3 slow pulses (repeated every 5 sec);
  yellow flashing at a rate of 0.5 Hz
- LOW priority
  1 pulse; yellow steady light

If more than one alarms are initiated shortly one after the other or at the same time, it is always the alarm with the highest priority that will be displayed. The acoustic signal is turned down after the alarm conditions have been removed, although the alarm remains displayed by an orange light and a text message until the confirmation by pressing the Alarm key. The alarm tone can be silenced for 2 minutes by pressing the Alarm key. During this period, also possible subsequent alarms are silenced with respect to the alarm tone. The alarm “Empty battery” is an exception and its alarm can in no situation be silenced. The alarm-LED keeps on displaying the alarm optically during the silenced alarm tone. If the alarm cause has not been removed, the acoustic alarm rings out again after two minutes. The volume of the acoustic signal can be set in 10 steps on the display of the advanced parameters.

The alarm tone can already be silenced before an alarm situation arises

by pressing the Alarm key e.g. before the tube system is shortly disconnected to carry out the suction of the patient. After the alarm cause has been removed, the alarm tone can also be reactivated within the two minutes by pressing the Alarm key once more.

The previous 15 alarms including the date of the alarm, the alarm time, the alarm cause and the measured values at the time of the alarm can be seen on the service screen of the device. Additionally, the alarms can be read out via the PC software. The alarm cause, the settings of the device and the alarm time are stored. Furthermore, the pressure and flow curves are stored from one minute before to one minute after the occurrence of the alarm cause.
Optionally, the alarms of middle and high priority can be transmitted to the remote alarm box.

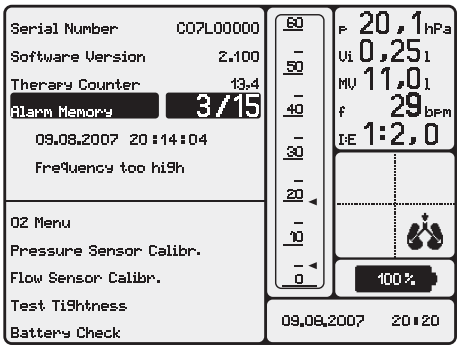


Figure 18: Selecting the alarm memory

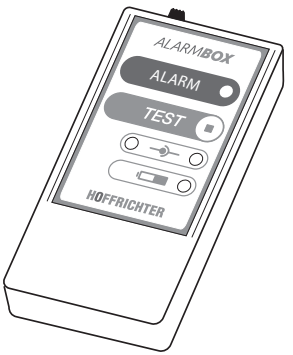


Figure 19: Remote Alarm Box

SAVING ALARMS

You can view the last 15 alarms directly in the service screen on the device. This provides the following information:

- Cause of the alarm
- Time of the alarm

The alarms can also be read out using CaratControl. In addition, the values measured at the time of the alarm can be viewed here. The memory depth is approximately 1 year.

TRANSMITTING ALARMS

Alarms can be transmitted by means of a nurse call or the optionally available remote alarm box. This allows even better monitoring of the device to be achieved in the home or clinic. The use of the remote alarm box or a nurse call is especially recommendable when several ventilators are used in one room, as this allows the device generating the alarm to be easily identified.

ADJUSTABLE ALARMS

IMPORTANT
Before changing alarm parameter settings, check the patient's condition.

If an adjustable alarm parameter (on the Standard display) results in an alarm, then it is simultaneously highlighted by a black bar.

Alarm / Message	Priority	Cause	Delay
Pressure too high	HIGH	Pressure higher than the set maximum pressure or positive pressure difference greater than the set difference	15 sec or 3 successive breaths
Pressure too low	HIGH	Pressure lower than the set minimum pressure or negative pressure difference greater than the set difference	15 sec or 3 successive breaths
Frequency too high	HIGH	The measured frequency exceeds the max. frequency	3 successive breaths
Volume too high	HIGH	Tidal volume higher than the max. volume	3 successive breaths
Volume too low	HIGH	PCV-/ PSV-/ SIMV-Mode: Tidal volume lower than the min. volume	3 successive breaths
		VCV-Mode: Volume smaller than the set volume, since "Max. pressure" has been reached	
Leakage	HIGH	Difference between expiration and inspiration volumes greater than the set leakage	
Oxygen too high	MEDIUM	Measured FiO_2 higher than the set max. oxygen	
Oxygen too low	MEDIUM	Measured FiO_2 ower than the set min. oxygen	
Min. Volume not reached	LOW	Tidal volume lower than the set min. volume	3 successive breaths

DEFINED ALARMS AND ERROR MESSAGES

ERROR MESSAGES OF THE HARDWARE TEST ON DEVICE START

Message	Cause	Remedy
Parameter Error	Invalid parameters / checksum error	Invalid parameters and settings have been detected and are reset to the factory settings; all ventilation and alarm parameters must be checked
Error RTC	General clock failure, invalid time, or invalid date	Date and time must be reset; if the clock is defective, device service is required
Sensor Error	Sensor signal outside of the valid range	Ventilation not possible or possible only to a limited degree; device service required
Incorrect Calibration Data	Invalid calibration data/checksum error	Ventilation possible; measured pressure and volume inaccurate; device service required
Error Int. Battery	Battery defective	Ventilation possible only with external power supply; device service required
Processor Error	Safety function of the controller not active	Ventilation possible; device service required

DEFINED POWER SUPPLY ALARMS

Alarm / Message	Priority	Cause	Remedy
Int. Battery discharged	HIGH	Battery discharged	The battery needs recharging; 1 minute until the power supply fails completely; ventilation possible only with external power supply
Error Int. Battery	MEDIUM	Battery defective	Device service required
Int. Battery low	MEDIUM	Battery capacity ≤ 10 %	The battery needs recharging

MISCELLANEOUS DEFINED ALARMS

Alarm / Message	Priority	Cause	Remedy
Leakage	HIGH	Inspiration flow too high for an extended period (> 15 sec)	Check the system for leaks in the tubing or the mask
Check Measuring Tube	HIGH	Pressure difference from 2nd pressure sensor greater than 3 hPa (> 15 sec)	Check the connection of the measuring tube to the connection port
Error Pressure Sensor	HIGH	Offset outside of range / calibration error / pressure constant over extended period (> 15 sec)	Device service required
Stenosis	HIGH	Measured tidal volume less than 30 ml Constant flow over a period of 15 sec.	Check the patient curcuit and the tube for occlusion
High Pressure	HIGH	Pressure higher than 60 hPa/device error → Emergency ventilation	Device service required
Device Error	HIGH (continuous tone)	Error in the communication between the controllers	Device service required
Error Oxygen Sensor	MEDIUM	Sensor defective / calibration error	Replace or recalibrate the oxygen sensor
Calibrate O_2 sensor	LOW	The O_2 sensor was fitted after the device has been turned on	Subsequent calibration via Service display required

ADDITIONAL MESSAGES

Message	Cause
Battery Operation	The device was disconnected from external power supply and is now operated by the internal battery; confirm message by pressing alarm key
Safety Mode	No spontaneous breathing on the patient's part; minimum frequency ensured by device; in PSV modes only
Saving Data Device is switching off	Data are saved after actuation of the main switch
Accept settings	The mode was changed during running ventilation; to activate a new mode, select this message by turning the MFK and then confirm the message by pressing the MFK
Communication active	Data are currently transferred from the system to the PC or vice versa
Stop Ventilation? YES / NO	The main switch has been activated during the ongoing respiration, acoustic signal is active; in order to terminate the respiration, the query must be confirmed with YES via the MFK
Attention! Main Switch OFF	The query if the respiration should be cancelled was confirmed with NO. The message stays until the main switch is turned on again
Press and hold key for 3 sec to turn ventilation off	The ON/OFF key has only been briefly pressed during the ongoing respiration; in order to terminate the respiration, this key must be pressed longer (> 3 sec)
Apnea limit set to > 15 sec	A value of > 15 sec has been selected for the apnea limit in the PSVmode. This indication must be confirmed by pressing the MFK

CLEANING AND DISINFECTION

- Disconnect the power plug before cleaning the ventilator.
- We do not recommend standard sterilization methods for the CARAT I ventilator.
- Do not use aggressive abrasive or other cleaners (e.g. acetone) for cleaning the ventilator.
- Do not immerse the ventilator in water or solvent.

DEVICE SURFACE

Use a cloth moistened with soap water to clean the external surfaces of the ventilator. Then wipe the ventilator with clear water to remove residual cleaning agent. When the ventilator is in clinical use, its surfaces should be disinfected at regular intervals and in case of suspected contamination. We recommend Mikrozid® Liquid for disinfecting the external surfaces of the ventilator. Disinfectants which are recognized according to the RKI Guideline can also be used. Before being put into operation, the ventilator should be completely dry.

AIR FILTER

IMPORTANT
Never operate the ventilator without air filter. Only and exclusively use original HOFFRICHTER filters.

Clean the coarse filter once a week. To do this, remove the filter cassette and take the coarse filter out of the cassette. To continue operation of the ventilator, insert a spare coarse filter or use a complete spare filter cassette. Wash out the coarse filter using mild soap water. Then thoroughly rinse with clear water. Before being re-inserted, the coarse filter must be completely dry. The white fine filter cannot be cleaned. It should be visually checked once a week and must be exchanged once a month or, if it is very dirty, even more often. To exchange the fine filter, remove the filter cassette and first take out the coarse filter. Then you can remove and exchange the fine filter.

PATIENT CIRCUIT AND MASK

Clean and disinfect reusable patient circuits and masks according to the manufacturer's instructions. If worn or damaged strongly, the patient circuit or the mask must be replaced. Dispose of any patient circuits that are not suitable for re-use.

OXYGEN SENSOR

Do not place the optional oxygen sensor in cleaning solution nor sterilize it. If necessary, the surface of the oxygen sensor may be wiped off with a damp cloth. Before being reconnected, the oxygen sensor must be completely dry.

HUMIDIFIER

Clean and disinfect any reusable humidifiers according to the manufacturer's instructions.

BACTERIAL FILTER

Exchange the bacterial filter at the intervals specified by the manufacturer. To exclude any biological contamination, bacterial filters should always be installed between the ventilator and the patient circuit, especially in case of clinical use.

REUSING THE VENTILATOR ON A DIFFERENT PATIENT

⚠WARNING

Before using the ventilator on a different patient, clean and disinfect it to such an extent that it is free from any human pathogens.

Please ensure that all tools used, such as measuring instruments and test lung, are free from human pathogens.

If MRSA contamination is suspected, the device must be packaged, with the appropriate labeling, and disinfected accordingly.

IMPORTANT

If the accessories (e.g., tube system, mask, filter, humidifier, etc.) are intended for repeated use, the manufacturer's provisions must be followed.

The reprocessing of the device acc. to procedure 1 and 2 should be documented.

REPROCESSING PROCEDURE 1

The following measures may only be carried out by companies with a QM system and appropriately qualified, authorized and experienced specialist personnel.

To reprocess the device, carry out the following steps:

- Properly dispose of the carrying case and, if necessary, the functional bag, as well as all accessory components that carry respiratory gas.
- Dismantle the device's sensor block. The sensor block's plastic parts are autoclaved. The sensors must not come into contact with cleaning fluids. A spray disinfection, e.g., using Mikrozid® Liquid, is possible. The sensors must be completely dry before replacing them in the sensor block.
- Disinfect all the parts of the housing and the connections with a suitable agent, e.g., Mikrozid® Liquid.
- Dispose of the filter cassette and replace it with a new one.

- Reassemble the device.
- After reprocessing, carry out a safety-related check according to this User's Manual (see page 76).
- Until the device is used again, store it safe from contamination with human pathogens.

REPROCESSING PROCEDURE 2

The following measures may only be carried out by companies with a QM system and appropriately qualified, authorized and experienced specialist personnel.

The hygienic reprocessing of the devices during a patient change can be carried out in accordance with the validated KR 1000 procedure. The type and scale of the reprocessing are described in detail in the "Instruction for validated respirators for the Desinfection System KR 1000". The number of reprocessing cycles for the device is limited to 10.

After reprocessing, carry out a safety-related check according to this User's Manual (see page 76).

REPROCESSING PROCEDURE 3

Procedure 3 can only be applied if the device was used with a bacterial filter at the inspiration port, and the bacterial filter was changed daily, or according to the manufacturer's instructions. This is the only way to ensure that the device is free of human pathogens.

To reprocess the device, carry out the following steps:

- Change the bacterial filter.
- Disinfect all the parts of the housing and the connections with a suitable agent, e.g., Mikrozid® Liquid.
- Change the coarse filter and the fine filter and disinfect the surface of the filter cassette. You can also replace the entire filter cassette with a new one.

FUNCTIONAL CHECK

⚠CAUTION
Whenever the ventilator is put into operation, the alarms must be checked for proper functioning beforehand.

The patient circuit to be used as well as a Siemens test lung are required for the functional check. Connect the patient circuit and the test lung to the ventilator. Connect the supplied power supply unit to the DC socket on the rear of the device and to the mains cable. Then connect the device to a voltage source via the mains cable. Turn on the ventilator by means of the main switch on its rear and start ventilation by pressing the control key.

Power failure alarm
Disconnect the ventilator from external power supply. An acoustical signal will be emitted, and the text field will display the message “Battery Operation”.

Leakage alarm
Disconnect the test lung from the system. After 15 seconds, an acoustic signal will be emitted and the text indication field will display the message “Leakage”.

Alarm: Frequency too high
Operate the ventilator in the PSV mode. Set the max. frequency alarm parameter higher than the frequency currently measured. Simulate spontaneous breathing using the test lung, until the acoustic alarm is initiated and the text indication field displays the message “Frequency too high”.

Alarm: Pressure too low
Operate the ventilator in the VCV mode. Set the value of the min. pressure alarm parameter higher than the maximum pressure reached. After 15 seconds, an acoustic signal will be emitted and the text indication field will display the message “Pressure too low”.

Alarm: Volume too low
Operate the ventilator in the VCV mode. Set the value of the max. pressure alarm parameter lower than the maximum pressure reached. After 15 seconds, an audible signal will be emitted and the text field will display the message “Volume too low”.

Alarm: Volume too low
Operate the ventilator in the PSV mode. Set the value of the min. volume alarm parameter higher than the volume measured. Set the minimum volume ventilation parameter to OFF. After 3 breaths, an acoustic signal will be emitted and the text indication field will display the message “Volume too low”.

Alarm: Volume too high
Operate the ventilator in the PSV mode. Set the value of the max. volume alarm parameter lower than the volume currently measured. Set the minimum volume ventilation parameter to OFF. After 3 breaths, an acoustic signal will be emitted and the text indication field will display the message “Volume too high”.

NOTICE
If one of the tests described above cannot be carried out, please contact your responsible service technician.

MAINTENANCE AND SAFETY-RELATED CHECK

IMPORTANT

In order to ensure the operating safety of the CARAT I ventilator, a safety-related test or maintenance must be carried out at the prescribed intervals.

Every six months, the CARAT I ventilator must be subjected to a safety-related check to be carried out by the authorized service agency. The safety-related check comprises

- a visual check for outside damage of the ventilator,
- a functional check and
- a check of the ventilation accessories for possible damage.

Moreover, the components required must be exchanged in the course of the safety-related check. These are contained in the maintenance kit.

Every twelve months, the ventilator must be subjected to maintenance measures. These measures include replacement of the components contained in the maintenance kit 1.

OPERATION BY EXTERNAL POWER SUPPLY AND BATTERY

The CARAT I ventilator automatically detects the voltage sources available. If the device is connected to an external voltage source via the power supply unit (PMC120 PS24 or SNP-A129-M), this is always used with the highest priority, and then the internal battery. The current voltage source is always indicated by the appropriate LED being lit.

OPERATION BY EXTERNAL POWER SUPPLY

IMPORTANT

Only the supplied power supply unit (PCM120 PS24 or SNP-A129-M) may be used for operating the ventilator by external power supply.

If the CARAT I ventilator is connected to a 100 - 250 V AC (-20 %, +10 %), 50/60 Hz voltage source via the power supply unit, the LED “external power supply” emits green light. This is also applicable if the main switch is turned off, because the internal battery is recharged if necessary. If the ventilator is disconnected from external power supply, an acoustic alarm is emitted with the ventilator on, the LED emits “yellow” light, and the text message “Battery Operation” is displayed. Confirm the message by pressing the MFK. Charging of the internal battery is indicated by the LED “Internal power supply” and the see-saw battery symbol.

OPERATION BY THE INTERNAL BATTERY

IMPORTANT

In order to prevent the internal battery from discharging, the ventilator should remain connected to external power supply in the standby mode.

Recharging of a completely discharged battery takes approx. 4 hours.

If CARAT I is turned on without any connection to external power supply or the device is disconnected from external power supply during running operation, an acoustic signal is emitted and the text indication field displays the message “Battery Operation”. Briefly press the Alarm key to turn

off the acoustical signal and to confirm the message.
Depending on the battery residual capacity, the “Internal power supply” LED is lit as follows:

LED color	Battery capacity
green	80 to 100 %
yellow	30 to 79 %
red	0 to 29 %

⚠WARNING
When the “Int. Battery discharged” alarm is triggered, the ventilator must be connected to an alternative power supply without delay.

Battery test

IMPORTANT
In order to ensure the operating safety of the CARAT I ventilator, a battery test must be carried out at the prescribed intervals.

To check the functionality of the internal battery, a battery test must be carried out monthly. To this end, operate the device with continuous ventilation for one hour, without a mains power supply. The capacity of the battery must then still be at least 10 %, i.e., the “Int. Battery low” alarm must not yet have been triggered. If the battery fails the test, it must be changed by an authorized service technician.

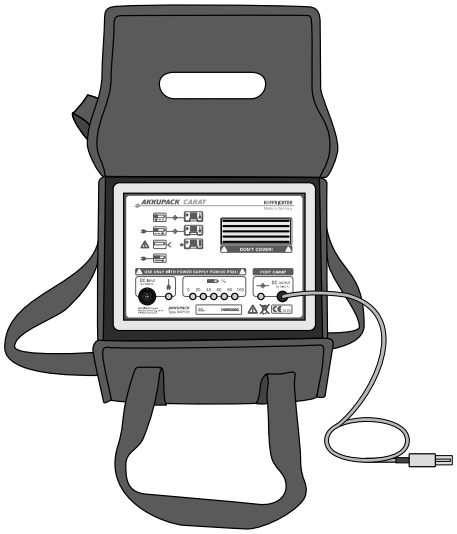


Figure 20: AKKUPACK CARAT

NOTICE

Only the HOFFRICHTER AKKUPACK CARAT may be used for the external power supply.
Before initial commissioning, you must read the User's Manual of the AKKUPACK CARAT.

The AKKUPACK CARAT enables the device to be operated independently of the mains power supply. The battery pack is optionally available as an accessory.

To supply the battery pack with power, use the power cable and the power supply unit of the ventilator.

At full capacity and factory settings, the battery pack enables operation for max. 12 h.

For further information on connecting and handling the device, please refer to the AKKUPACK CARAT User's Manual.

DISPOSAL

DEVICE

The ventilator must not be disposed of with the household waste. Please contact the relevant customer services department to find out how to dispose of the device properly.

Proper disposal saves natural resources and prevents harmful substances being released into the environment.

PACKAGING

The packaging is taken back by the distributor but it can alternatively be disposed of separately in the normal household waste.

BATTERIES

Exchanged batteries must be recycled in accordance with battery regulations. Please contact the relevant customer services department to find out how to dispose of the device, etc. properly.

OXYGEN SENSOR

The oxygen sensor must not be disposed of with the household waste. Please contact the relevant customer services department to find out how to dispose of the device, etc. properly.

ACCESSORIES

Scope of delivery	Article number
Carrying case	0000 4875
Power supply (cable approx. 1.83 m)	0000 4206
Mains cable (approx. 1.80 m)	3110 0013
Single line patient circuit 22 mm (1.80 m), complete with adapter for expiration connection	0000 7967
Filter cassette	0000 4880
2 pack coarse filter	0000 4950
5 pack fine filter	0000 4951
Adapter for bacterial filter	0000 4933
Adapter for oxygen connection, straight	4100 0104
User's manual	5000 0102
Short manual	0000 4851

Optional	Article number
FiO_2 measurement set (oxygen sensor, T-adapter, housing gas duct, oxygen sensor connection cable)	0000 4944
Oxygen sensor	2300 0018
T-Adapter	2300 0019
Housing gas duct	2300 0020
Oxygen sensor connection cable	0001 4116
Oxygen connection adapter, angled	4100 0087
Control tube connection adapter	4100 0088
Functional bag	0000 4879
AKKUPACK CARAT incl.accessories	0000 4030
Remote Alarm Box	0000 4035

TECHNICAL DATA

Voltage suppllies	
Mains power	100 ... 250 V AC (-20 %, +10 %), 50 ... 60 Hz
DC power	24 V DC / 5 A
Internal battery power	Lithium ion battery, 28,8 V (nominal voltage) / 2.25 Ah / 3 W
External battery power	AKKUPACK CARAT 24 V (nominal voltage) / 5 A
Maximum power consumption	60 W
Electric safety class	Class II, type BF

Factory settings	
Mode	PCV
Display I:E	I:E
Display Pressure Unit	hPa
Display Screen	STD
Safety lock (software)	manually
Safety lock	OFF
Alarm Volume	50 %
Pressure Difference	3.0 hPa
Max. Inspiration time	4 sec
Leakage	OFF
Max. Oxygen	OFF
Min. Oxygen	OFF
Language	ENG

Specifications and Performance	
Dimensions (W x D x H)	305 x 250 x 165 mm
Weight	4.6 kg
Max. stable pressure limit	60 hPa
Min. stable pressure limit	0 hPa

Specifications and Performance	
Max. working pressure	50 hPa
Min. working pressure	0 hPa
Maximum flow	250 l/min

Measured values				
Parameter	Display range	Increments of the display	Measurement	Accuracy
Pressure	0.0 to 99.9 hPa	0.1 hPa	0.0 to 100 hPa	0.1 hPa
Pressure bargraph	0.0 to 60.0 hPa	5 hPa	0.0 to 100 hPa	0.1 hPa
Volume	0.0 to 2.5 hPa	0.01 l	Calculated from flow measurement	
Flow	-	-	0 to 200 l/min	0.2 l/min
Oxygen	0 to 100 %	1 %	0 to 100 %	0.3 %
Frequency	0 to 99 bpm	1 bpm	Calculated from period duration of inspiration + expiration in 0.002 s	

Maximum Minute Volume	
PCV mode (IPAP = 50, PEEP = 0)	
R5 / C50	45 l/min
R5 / C20	33 l/min
R20 / C20	26 l/min
R20 / C50	30 l/min
VCV mode	limited to 90 l/min

Sound pressure range of audible alarm signal	
Lowest value (at 1 m distance)	64 dBA, setting 10 %
Highest value (at 1 m distance)	79 dBA, setting 100 %

Resistances	
Inspiratory resistance of the device at the patient connection port	3.6 hPa with 60 l/min
Total system resistance	< 6 hPa with 60 l/min

Operating Conditions	
Operating temperature	- 5 °C to + 50 °C
Relative air humidity	10 % ... 95 %
Operating conditions	600 hPa ... 1000 hPa

Storage	
Storage temperature	- 10 °C to + 50 °C
Storage conditions	store in a dry, vibration-free and vertical position; store device and accessories in their original packing

Technical Requirements for Accessories (CE mark required!)	
Oxygen Inlet	
Type of connection port	Quick coupling
Pressure	< 200 hPa
Flow	< 15 l/min
Bacterial Filter	
Connections	22 / 15 mm cone (acc. to EN1281-1)
Resistance	< 2.3 hPa with 60 l/min
Compressible volume	< 66 ml
Internal volume	< 200 ml

The system complies with the following standards and guidelines:

- Directive 93/42/ECC
- DIN EN 60601-1
- DIN EN 60601-1-2
- DIN EN 60601-1-4
- DIN EN 60601-1-8
- DIN EN ISO 14971
- DIN EN ISO 10651-6
- DIN EN 1041
- DIN EN 980
- DIN EN 13328-2
- ISO/DIS 15001
- ANSI F1246-91

CE marking as per EC directive 93/42/EEC.
The manufacturer reserves the right to make technical changes without notice.

MANUFACTURER'S DECLARATION ON ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions		
The CARAT I ventilator is intended for use in the electromagnetic environment specified below. The user [1] of the CARAT I ventilator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions acc. to CISPR 16-1-2	Group 1	The CARAT I ventilator uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions acc. to CISPR 16-1-2	Class B	The CARAT I ventilator is suitable in all establishments, including domestic establishments and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissons acc. to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions acc. to IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The CARAT I ventilator is intended for use in the electromagnetic environment specified below. The user [1] of the CARAT I ventilator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient (Burst) acc. to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output	± 2 kV for power supply lines ± 1 kV for input / output	Mains power quality should be that of a typical commercial or hospital environment.
Surges acc. to IEC 61000-4-5	± 1 kV voltage outer conductor - outer conductor ± 2 kV voltage outer conductor - ground	± 1 kV voltage outer conductor - outer conductor ± 2 kV voltage outer conductor - ground	Mains power quality should be that of a typical commercial or hospital environment.

1 Here “user” is meant in the sense of “Responsible Organization”

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines acc. to IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 1/2 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	> 95 % dip inder U_T for 1/2 cycle 60 % dip in U_T for 5 cycles 30 % dip in U_T for 25 cycles > 95 % dip in U_T for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CARAT I ventilator requires continued operation during power mains interruption, it is recommended that the CARAT I ventilator is powered from an UPS or a battery.
Power frequency (50/60) Hz magnetic field acc. to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF acc. to IEC 61000-4-6	10 $V_{effective\ value}$ 150 kHz – 80 MHz within the ISM bands [a]	10 V	Portable and mobile communications equipment should be used no closer to any part of the CARAT I ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended safety clearance: $d = 1.2 \sqrt{P}$

Guidance and manufacturer's declaration – electromagnetic immunity			
Radiated RF acc. to IEC 61000-4-3	10 V/m 80 MHz – 2,5 GHz	10 V/m	d = 1.2 √P for 80 MHz to 800 MHz d = 2.3 √P for 800 MHz to 2,5 GHz with *P* as the rated maximum output power of the transmitter in watts (W), according to the transmitter's manufacturer, and *d* as the recommended safety clearance in meters (m) [b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [c], should be less than the compliance level in each frequency range [d]. Interference may occur in the vicinity of equipment marked with the following symbol. 

Note 1 U_T is the a.c. mains voltage prior to application of the test level.

Note 2 At 80 MHz and 800 MHz the higher frequency range is essential.

Note 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz and 2.5 GHz are intended to reduce the probability that mobile/portable communication facilities can cause interference when they are accidentally brought into the range of the patient. For this reason, the additional factor of 10/3 is applied in the calculation of the recommended safety clearances in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic side survey should be considered. If the measured field strength outside the location in which the CARAT I ventilator is used exceeds the compliance level, the CARAT I ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures my be necessary, such as relocating or using another location of the CARAT I ventilator.

[d] Over the frequency range of 150 kHz to 80 MHz, the field intensity should be less than [U_1] V/m.

Recommended separation distances between portable and mobile RF communication equipment and the CARAT I			
The CARAT I ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the CARAT I ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CARAT I ventilator as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz – 80 MHz $d = 1.2 \sqrt{P}$	**80 MHz – 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz – 2,5 GHz** $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.27
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1 At 80 MHz and 800 MHz the higher frequency range is essential.			
Note 2 The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.			
Note 3 The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz and 2.5 GHz are intended to reduce the probability that mobile/portable communication facilities can cause interference when they are accidentally brought into the range of the patient. For this reason, the additional factor of 10/3 is applied in the calculation of the recommended safety clearances in these frequency ranges.			
Note 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

DISCLAIMER

HOFFRICHTER GmbH is not liable for consequences in terms of safety, reliability and performance of the product if:

- interventions, modifications, extensions, calibration, repairs and maintenance are carried out by persons not authorized by us,
- other manufacturers' accessories and spare parts are used that have not been approved by us for use on the product,
- the product is used other than as described in the user's manual or
- the hygiene and cleaning instructions described in the user's manual have not been complied with.

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